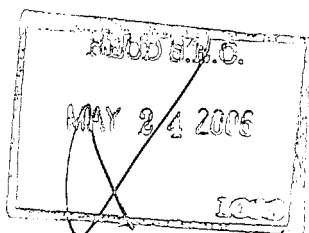
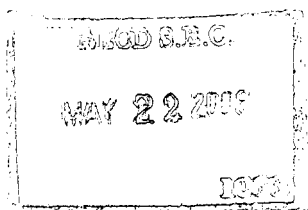


AtriCure 2005  
Annual Report

Developing advanced products for the  
treatment of atrial fibrillation.

P.E  
12-31-05

ATRICURE Inc



06037743

PROCESSED

JUN 12 2006 E

THOMSON  
FINANCIAL

ablation (AF) a tried, true, proven procedure  
The mission of the team is the most  
sustained cardiac arrhythmia

more than five million people worldwide, including  
over 2.5 million people in the U.S., where approximately  
over 600,000 cases of AF are diagnosed each year

\$10 billion per year is spent annually in the U.S.  
on AF-related healthcare costs.

For many people over the age of 40 in the U.S.,  
the primary risk of developing AF, and the incidence  
increases with age.

AF patients are five times more likely to have a stroke

and who have a stroke related to AF are two times  
likely to be bedridden.

AtriCure is working to expand treatment options for AF patients.

#### RECENT DISPOSABLE PRODUCTS

#### ATRICURE ASU

Phoenix Ablation Clamp

Wolf™ Lumino™ Dissector

Isaktor™ Bipolar Pen

Ablation & Sensing Unit



AF is a complex condition that can be challenging to treat. AtriCure is committed to providing the most advanced, effective, and safe treatment options for AF patients. Our team of experts is working to expand our portfolio of products to meet the needs of our patients and our healthcare providers.

For more information on AtriCure's AF treatment options, please visit our website at [www.atricure.com](http://www.atricure.com) or contact your local AtriCure representative.

AtriCure is a leader in the field of cardiac ablation and is committed to providing the most advanced, effective, and safe treatment options for AF patients.

Our team of experts is working to expand our portfolio of products to meet the needs of our patients and our healthcare providers.

---

## To our stockholders:

This past year was extremely successful by several measures as we reinforced our leadership position in the development and commercialization of technologies that physicians have adopted for the surgical treatment of patients suffering from atrial fibrillation (AF).

Some of our accomplishments this past year included:

- Generating \$31.0 million in revenue, a more than 60% increase over 2004, including revenue of \$6.4 million in worldwide sales of products used in minimally invasive sole-therapy (MIST) procedures;
- Surgeons performing MIST procedures in over 55 medical centers during the fourth quarter;
- Receiving FDA clearance for our endoscopic ablation platform to facilitate adoption of MIST procedures;
- Launching the Isolator™ bipolar pen with a cardiac tissue indication, further expanding our ablation platform;
- Enrolling 70% of patients required for our RESTORE SR-II feasibility trial for the evaluation of our MIST platform, facilitating progress toward our pivotal trial;
- Completing an initial public offering that raised \$43.0 million in net proceeds; and
- Acquiring the supplier of our disposable products, strengthening our engineering capacity and increasing our gross margins.

These accomplishments were made possible by the men and women of AtriCure who are devoted to improving the lives of patients. Their commitment to innovation and passion for expanding treatment options for patients suffering from AF combined with their allegiance to our Company represents the foundation for our success.

### Advanced Product Offering Driving Increased Adoption

The medical community is increasingly recognizing the benefits of our products which is leading to their rapid adoption. Encouraging results of clinical studies involving our bipolar ablation system, combined with its simplicity, reliability and ease of use, have made it a preferred treatment alternative. The medical literature indicates that our innovative clamp design safely and reliably creates precise scars that block the abnormal electrical impulses that cause AF with minimal risk of thermal injury to surrounding tissues and structures.

Published reports suggest that our ablation treatment adds only approximately 20 minutes to open-heart procedures and when used during MIST procedures, surgeons have successfully treated patients in approximately two hours.

### Addressing \$2 Billion U.S. Market Opportunity

While we remain the leader in the concomitant open-heart surgical AF market, our most significant long-term opportunity for growth is the large and growing minimally invasive sole-therapy market.

According to the medical literature, treatment options for AF patients over the past decade have been largely ineffective and technically challenging. The most common treatment for these patients has been drug therapy, which is often ineffective and has adverse side effects. Until recently, surgical procedures have been difficult to perform, highly invasive and associated with long recovery times. Catheter procedures to treat AF have also not been widely adopted due to the complexity and length of the procedures, safety concerns and reports of inconsistent patient outcomes.

Due to the limitations of current treatment options, we believe we are particularly well-positioned to capitalize on the urgent need for AF treatment alternatives. Our leadership position in the open-heart market is paving the way for us to launch and further develop our MIST platform to address this large unmet need.

Currently, 2.4 million Americans have been diagnosed with AF, with one in four people over the age of 40 at risk of developing AF. AF patients are five times more likely to have a stroke and the cost to our healthcare system is \$6 billion annually and rising. Of this total patient population, more than 300,000 are candidates for our MIST procedure, which translates into a U.S. market opportunity of more than \$2 billion. We believe the international market opportunity is equal in size.

---

#### AF MARKET OPPORTUNITY

---

##### Open-Heart Surgery

400,000

Annual procedures (U.S.)

80,000

AF patient pool

\$198M

AtriCure opportunity

---

##### Minimally Invasive Surgery

2,400,000

AF population (U.S.)

300,000

Sole-therapy patient pool

\$2B

AtriCure opportunity

---

### Generating Clinical Data To Drive Momentum

Recognizing the importance of clinical data and FDA approvals to drive market penetration of our MIST platform, we are conducting the RESTORE SR-II trial, the only FDA-regulated clinical study evaluating a minimally invasive sole-therapy surgical treatment of AF. We expect to complete patient enrollment in the feasibility phase of this study in the second quarter of 2006 and report results throughout the year. Because our investigators are enthusiastic and encouraged by the initial results of this study, we have begun working with the FDA to initiate a pivotal clinical trial to gain FDA approval of our MIST products.

We also anticipate results during the year of several other ongoing physician-sponsored studies being conducted at leading institutions that could further demonstrate the benefits of our technology and facilitate wider adoption of MIST surgical procedures for AF.

### Leading the Advancement of AF Treatment

We have a comprehensive and innovative product development plan. Late last year, we received FDA clearance for our Isolator endoscopic ablation platform. This platform, which was designed to further simplify our minimally invasive ablation procedure and make it more broadly adoptable, also enables a completely thorascopic MIST procedure. Additionally, we have plans to launch several enhanced versions of our endoscopic ablation platform during 2006 and 2007.

The AtriCure Cosgrove-Gillinov Clip, our left-atrial-appendage exclusion product, has the potential to further expand the market for our MIST procedure. Studies have shown that the left atrial appendage is the leading cause of thrombus in patients diagnosed with AF and it is believed that exclusion of the left atrial appendage may reduce the risk of AF-related strokes. We plan a limited release of the first version of the Cosgrove-Gillinov Clip in the second half of 2006.

We are also developing a high-intensity focused ultrasound (HIFU) ablation probe designed to complement our Isolator endoscopic ablation platform. Our objective with this technology is to expand our ablation treatment, potentially providing a more efficacious solution for patients with more continuous AF.

### Driving Future Innovation

We are committed to staying at the forefront of innovation to enhance, expand and facilitate the surgical treatment of AF. To accomplish this, we intend to play a major role in collaborative research and development efforts, such as the AF Innovation Center, which the State of Ohio is funding with a \$23.0 million grant. Through the Innovation Center, we will be working with such thought-leading institutions as the Cleveland Clinic, Case Western Reserve and the University of Cincinnati.

Research at the Innovation Center will, among other things, focus on the development of an epicardial mapping system that is anticipated to provide new insights into the mechanisms of AF and potentially enable surgeons to customize ablation treatment on a patient-by-patient basis. The Center will also conduct clinical trials to answer crucial AF patient management questions, such as the impact of left-atrial-appendage exclusion on atrial function and reduction of AF-related strokes.

Finally, the Center plans to develop advanced training programs and processes to facilitate clinical studies and general clinical use of minimally invasive surgical approaches. We anticipate these and other initiatives will lead to a steady flow of data and landmark publications that significantly advance the treatment of AF.

Our progress in 2005 has established a solid platform for growth of our market leading technologies. We expect 2006 to be a critical year as we work to further establish MIST as a standard treatment alternative and strive to provide more comprehensive treatment solutions.

We appreciate your continued support which enables us to fulfill our vision of making important contributions to improving the lives of patients who suffer from AF.

Sincerely,



David Jay Drachman  
President and Chief Executive Officer



### THE ATRICURE SOLUTION

#### Surgeon Adoption for AF

25,000

Procedures performed

#### Market Share

50%

Surgical ablation AF market

#### Minimally Invasive Sole-Therapy (MIST) Highlights

55

Centers which performed MIST  
procedures in fourth quarter 2005

2 hrs

Surgeon-reported MIST  
procedure times

#### Financial Highlights

\$31M

61.6% year-over-year  
revenue growth

\$6.4M

2005 MIST revenue

Form 10-K

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

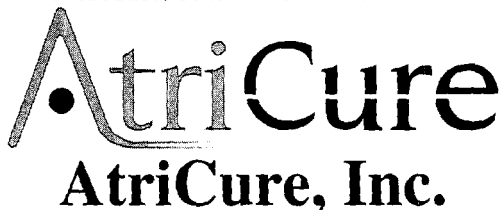
**FORM 10-K**

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 000-51470



(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**6033 Schumacher Park Drive, West Chester, OH**  
(Address of principal executive offices)

**34-1940305**

(I.R.S. Employer  
Identification Number)

**45069**  
(Zip Code)

**Registrant's telephone number including area code: (513) 755-4100**

**Securities Registered Pursuant to Section 12(b) of the Act:**

Title of each class

None

Name of each exchange on which registered

N/A

**Securities Registered Pursuant to Section 12(g) of the Act:**

**Common Stock, \$.001 Par Value Per Share**

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting Common Stock held by non-affiliates of the registrant, based upon the closing sale price of the Common Stock on December 30, 2005 (which is the last business day of the registrant's most recently completed fourth fiscal quarter), as reported on the Nasdaq National Market was approximately \$45.6 million. We were not a reporting company as of June 30, 2005. Shares of Common Stock held by each executive officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 15, 2006, there were outstanding 12,117,337 shares of Common Stock, \$.001 par value.

**DOCUMENTS INCORPORATED BY REFERENCE**

Items 10, 11, 12, 13 and 14 of Part III of this Form 10-K incorporate information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this Form 10-K.

## TABLE OF CONTENTS

	<u>Page Number</u>
PART I .....	1
ITEM 1: Business .....	1
ITEM 1A: Risk Factors .....	24
ITEM 1B: Unresolved Staff Comments .....	45
ITEM 2: Properties .....	45
ITEM 3: Legal Proceedings .....	45
ITEM 4: Submission of Matters to a Vote of Security Holders Executive Officers of the Registrant .....	46
PART II .....	49
ITEM 5: Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities .....	49
ITEM 6: Selected Financial Data .....	51
ITEM 7: Management's Discussion and Analysis of Financial Condition and Results of Operations .....	52
ITEM 7A: Quantitative and Qualitative Disclosures About Market Risk .....	62
ITEM 8: Financial Statements and Supplementary Data .....	63
ITEM 9: Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	86
ITEM 9A: Controls and Procedures .....	86
ITEM 9B: Other Information .....	86
PART III .....	87
ITEM 10: Directors and Executive Officers of the Registrant .....	87
ITEM 11: Executive Compensation .....	87
ITEM 12: Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	87
ITEM 13: Certain Relationships and Related Transactions .....	87
ITEM 14: Principal Accountant Fees and Services .....	87
PART IV .....	88
ITEM 15: Exhibits and Financial Statement Schedules .....	88
SIGNATURES .....	90

## PART I

*This Form 10-K, including the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," contains forward-looking statements regarding our future performance. All forward-looking information is inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Form 10-K. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Form 10-K other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "anticipate" and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. With respect to the forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. These forward-looking statements speak only as of the date of this Form 10-K. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise.*

### ITEM 1. BUSINESS

#### Overview

We develop, manufacture and sell innovative surgical devices designed to create precise lesions, or scars, in cardiac and soft tissues. Medical journals have described the adoption by leading cardiothoracic surgeons of the AtriCure bipolar ablation system as a standard treatment alternative during open-heart surgical procedures to safely, rapidly and reliably create lesions in cardiac, or heart, tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart. AF is associated with an increased risk of stroke and is often accompanied by such symptoms as fatigue, shortness of breath and heart palpitations. Sales of our products reached approximately \$9.8 million for 2003, the first full year of general sales of our products, approximately \$19.2 million for 2004, and approximately \$31.0 million for 2005.

Cardiothoracic surgeons have adopted our system to treat AF in over 25,000 patients since its general commercial release in the United States in January 2003. We believe that the AtriCure bipolar ablation system is currently a market leader in the surgical treatment of AF during open-heart surgical procedures, such as bypass or valve surgery, and surgeons have used our system as a sole-therapy minimally invasive treatment for AF, which is performed on patients who are not undergoing a separate open-heart procedure, on over 800 patients. Our system is currently being used in 23 of the 25 highest volume heart centers in the United States. We do not believe that our system is currently being used for its Food and Drug Administration, or FDA, cleared indications, and, accordingly, substantially all of our revenue is currently generated through the non-FDA-approved, or off-label, use of our system for the treatment of AF.

The AtriCure bipolar ablation system, our primary product, consists of a compact power generator known as an ablation sensing unit, or ASU, and several uniquely designed disposable ablation clamps that connect to the ASU, including two newly developed Isolator endoscopic ablation clamps that are specifically designed for use in sole-therapy minimally invasive procedures. We also market the Isolator bipolar pen and the Wolf dissector, which are separate from, but complement, our system and we distribute cryoablation systems that use extreme cold to ablate tissue.

AF is the most common sustained cardiac arrhythmia, or irregular heartbeat, encountered in clinical practice and accounts for more doctor visits and hospital days than any other cardiac arrhythmia. According to the Framingham Study published in 2004, one in four people over the age of 40 in the United States has a lifetime



risk of developing AF, and the incidence of AF increases with age. More than five million people worldwide, including approximately 2.4 million Americans, are currently afflicted with AF. According to the American Heart Association, approximately 15% to 20% of the estimated 700,000 strokes that occur annually in the United States are attributable to AF and people with AF are approximately five times more likely to have a stroke.

AF is a condition that doctors often find difficult to treat, and historically there has been no widely accepted cure for AF. Doctors typically begin treating AF with drugs, which are often ineffective, not well-tolerated and may be associated with serious side effects. Patients who cannot effectively be treated with drugs occasionally undergo catheter-based procedures to treat their AF, but catheter-based procedures have not been widely adopted because they are technically challenging, can be associated with serious complications and yield inconsistent results. Implantable devices, such as pacemakers and defibrillators, are sometimes used to reduce the frequency and symptoms of AF, although they do not treat the underlying disease. In the past, an open-heart surgical procedure known as the classic Maze was used to treat AF, but this procedure has not been widely adopted because it is technically challenging, highly invasive and involves long recovery times.

The creation of transmural, or full-thickness, lesions is thought to be a critical factor in the successful treatment of AF when performing ablation treatments. Prominent medical journals, which contain articles that were written, in part, by leading cardiothoracic surgeons who are consultants to us, describe how cardiothoracic surgeons have used our system to safely, rapidly and reliably create transmural lesions when treating AF either during an elective open-heart surgical procedure, such as bypass or valve surgery, or as a sole-therapy minimally invasive procedure. As indicated in these studies, cardiothoracic surgeons using our system have created individual transmural lesions in the heart in a matter of seconds and have treated AF in approximately 20 minutes during open-heart surgical procedures and in approximately two to three hours as a sole-therapy minimally invasive procedure.

The FDA has cleared the AtriCure bipolar ablation system for the ablation, or destruction, of soft tissues in general and non-cardiac related surgical procedures but to date has not cleared or approved our system for cardiac use or for the treatment of AF. In June 2005, the FDA denied 510(k) clearance for use of our system to ablate cardiac tissue because the FDA determined that our system is not substantially equivalent to an already FDA-cleared device. The FDA has taken a position that no radio-frequency surgical clamps are general cardiac tools because radio-frequency surgical clamps are specifically designed and intended for use in surgical ablation to treat AF. As such, no radio-frequency surgical clamps from any medical device company, including ours, have been cleared for cardiac ablation to date. This means that we would now be required to gain FDA approval to market the device through the submission of a pre-market approval application, or PMA, a lengthier process, in order to gain FDA approval of our system for the cardiac indication. While we may appeal the FDA's decision, receipt of that 510(k) clearance would not eliminate the need to seek FDA approval through a separate PMA for the use of our system to treat AF. After conducting necessary clinical trials, we intend to seek FDA approval as early as 2009 for the use of our system to treat AF, which we view as our market opportunity. We did receive FDA clearance in June 2005 for the use of our Isolator bipolar pen for the surgical ablation of cardiac tissue, and we believe that cardiothoracic surgeons will use our pen device for that use.

Although the use of our system to treat AF remains investigational and we are still seeking FDA approval in connection with use of our system for the treatment of AF, preliminary clinical studies conducted by doctors at leading cardiac care centers provide support for our system's ability to safely, rapidly and reliably create the lesions needed to block the abnormal electrical impulses that cause AF. We believe that those studies indicate that we have a significant competitive advantage in the treatment of AF. Several preliminary clinical studies, including a 27-patient study, a 40-patient study, a 47-patient study and a 276-patient study, in which several of our consultants participated and that were published in *The Journal of Thoracic and Cardiovascular Surgery*, found that approximately 90% of study participants treated using our system were free of AF at six-month follow-up. This success rate was achieved both when our system was used as a sole-therapy minimally invasive approach and when it was used during open-heart surgical procedures. We believe the overall demand for our system will increase, including demand for our system as a sole-therapy minimally invasive AF treatment, which we believe will ultimately represent our largest growth opportunity.

Information about our operating results and working capital practices is incorporated by reference to the information set forth in Item 7 of this Form 10-K.

## Market Overview

AF is a condition where abnormal electrical impulses cause the atria, or upper chambers of the heart, to fibrillate, or quiver, at rapid rates of 400 to 600 times per minute. As a result of this quivering, blood in the atria becomes static, creating an increased risk that a blood clot will form and cause a stroke or other serious complications. If AF persists, patients generally progress from experiencing AF intermittently to having AF continuously, a condition that is more difficult to treat. Symptoms of AF may include heart palpitations, dizziness, fatigue and shortness of breath, and these symptoms may be debilitating and life threatening in some cases. Although there is often no apparent cause of a patient's AF, the condition is often associated with high blood pressure and other forms of heart disease.

AF is the most commonly diagnosed sustained cardiac arrhythmia, and affects more than five million people worldwide, including more than 2.4 million Americans, where approximately 160,000 new cases of AF are diagnosed each year. According to an article in the April 2001 edition of *The New England Journal of Medicine*, it is estimated that the incidence of AF doubles with each decade of an adult's life. AF affects approximately 6% of all people 65 years and older in the United States. Studies show that one in four people over the age of 40 in the United States has a lifetime risk of developing AF, and the incidence of AF increases with age.

According to the American Heart Association, people with AF are about five times more likely to have a stroke, and AF is thought to be responsible for approximately 15% to 20% of the estimated 700,000 strokes that occur annually in the United States. According to the National Center for Health Statistics, AF also accounts for an estimated 3.2 million office visits and more than 465,000 hospitalizations annually in the United States. According to *Medtech Insight*, AF accounts for more than \$6 billion in healthcare costs each year in the United States. According to the *Journal of the American Medical Association*, the number of patients with AF in the United States will continue to increase. AF is an underdiagnosed condition due in large part to the fact that patients with AF often have mild or no symptoms, and their AF is only diagnosed when they seek treatment for an associated condition, such as a stroke or heart disease. We believe that increasing awareness of AF and improved diagnostic screening will result in an increase in the number of patients diagnosed with AF. Also, since the prevalence of AF increases with age, there will likely be an increase in the number of diagnosed AF patients in the United States as the population ages. Of the patients undergoing open-heart surgery in the United States, we estimate that approximately 75,000 of these patients are candidates for surgical ablation using our system.

Of the United States population diagnosed with AF, approximately 12% of these patients are symptomatic and do not respond to drug therapy or are intolerant to the drugs used to treat AF. For these patients, the classic Maze procedure is typically too invasive and catheter-based treatments have not been widely adopted. Accordingly, we believe that there is a large population of undertreated patients who would potentially benefit from sole-therapy minimally invasive AF treatment using our system, and that these patients will ultimately comprise our largest growth opportunity.

Because the FDA has not cleared or approved our system for the ablation of cardiac tissue or the treatment of AF, we and others acting on our behalf may not promote our system for these uses, make any claim that our system is safe and effective for these uses or train doctors to use our system for these uses outside of the clinical trial setting. However, these restrictions do not prevent doctors from choosing to use our system for the treatment of AF or prevent us from engaging in sales and marketing efforts that focus only on the general attributes of our system and its FDA-cleared uses and not on the ablation of cardiac tissue or the treatment of AF. Although we educate and train doctors as to the general skills involved in the proper use of our system and its technology, we do not educate or train them to use our system for the ablation of cardiac tissue or the surgical treatment of AF. However, we consider requests and often support physician training by providing educational grants for independent third-party university and physician programs. Because the FDA has cleared our pen device for the

surgical ablation of cardiac tissue, we may promote this device to doctors and provide education and training on the use of our pen device for the surgical ablation of cardiac tissue.

### **Current Treatment Alternatives**

Doctors usually begin treating AF patients with a variety of drugs intended to prevent blood clots, control heart rate or restore the heart to normal rhythm. If a patient's AF cannot be adequately treated with drug therapy, doctors may perform one of several procedures that vary depending on the severity of the AF and whether the patient suffers from other forms of heart disease. Current AF treatment alternatives to the use of our system for surgical ablation during an open-heart surgical procedure or as a sole-therapy minimally invasive procedure generally consist of the following:

- *Drugs.* Currently available drugs are often ineffective, not well-tolerated and may be associated with severe side effects. For these reasons, drug therapy for AF fails for as many as 50% of patients within two years. Of those who initially respond to drug therapy, only approximately 25% of patients can continue to be managed with drugs after five years.
- *Implantable Devices.* Implantable devices, such as defibrillators and pacemakers, can be effective in reducing the symptoms and number of AF episodes, but neither device is intended to treat AF. Patients may continue to experience the adverse effects of AF as well as some of the symptoms, including dizziness and fatigue, because the AF continues.
- *Catheter-Based Treatment.* Catheter-based AF treatments are technically challenging, can be associated with serious complications and yield inconsistent results. For these reasons, catheter-based procedures have not been widely adopted. In proportion to the prevalence of AF, only a small number of catheter-based AF treatments are performed each year in the United States.
- *Classic Maze.* The classic Maze procedure is a highly invasive open-heart surgical procedure that involves the use of a heart-lung bypass machine and cutting and sewing back together sections of the heart in order to block the abnormal electrical impulses causing AF. Although this procedure is highly effective at treating AF, it is rarely performed because it requires extensive open-heart surgery, is technically challenging and is typically associated with long recovery times. For these reasons, only a limited number of these procedures have been performed by a small number of cardiothoracic surgeons.

### **The AtriCure Solution**

We believe that traditional surgical and catheter-based ablation devices are not able to safely, rapidly and reliably create the transmural lesions required to block the abnormal electrical impulses that cause AF. Reports of preliminary clinical studies conducted by doctors at prominent cardiac care centers indicate that cardiothoracic surgeons have adopted the AtriCure bipolar ablation system for the treatment of AF during elective open-heart surgical procedures. These reports suggest that our system allows cardiothoracic surgeons to simplify the classic Maze procedure with a faster, less invasive and less technically challenging approach that appears to have comparable effectiveness, which we believe has led to our system's high market penetration and rapid adoption. Some leading cardiothoracic surgeons have also commenced use of our system as a sole-therapy minimally invasive treatment for AF.

Leading cardiothoracic surgeons who are consultants to us have participated in the preliminary clinical studies that were conducted at prominent cardiac care centers, such as the Cleveland Clinic, Washington University and the University of Cincinnati. These studies, which included approximately 700 patients in total, were conducted to evaluate the efficacy, ease of use and safety of our system.

**Efficacy.** AF treatment devices must be able to reliably create transmural lesions in order to reliably block the electrical impulses that trigger and sustain AF. Transmurality is considered by many physicians to be necessary for the treatment of AF, since creating lesions with gaps can fail to treat AF and cause other abnormal

heart rhythms. The studies described above found that between 80% and 95% of the study participants treated for AF using our system were free of AF at a six-month follow-up. We are seeking to confirm these results in the FDA-approved clinical trial for the use of our system during elective open-heart surgery and in a feasibility study for the use of our system as a sole-therapy minimally invasive treatment.

**Ease of Use.** In these studies, cardiothoracic surgeons reported that our system is easy to use, based in part on the design and automated features of our ablation and sensing unit, or ASU. Our ASU does not require the surgeon to make any prior settings or adjustments, and signals the surgeon when the targeted tissue no longer conducts energy, indicating that the lesion is transmural, or full-thickness. Our system's unique jaws firmly clamp and compress the targeted tissue being ablated, allowing surgeons to create in a matter of seconds transmural lesions that are required to block the abnormal electrical impulses that cause AF. Cardiothoracic surgeons report that they have generally treated AF in only 20 minutes when using our system during an open-heart procedure, or in approximately three hours when using our system to treat AF as a sole-therapy minimally invasive procedure.

**Safety.** Although serious complications, including death, may arise from any type of cardiac surgery, our system was found to be a safe treatment alternative for the surgical treatment of AF in these studies. Cardiothoracic surgeons participating in these studies concluded that our system reduced the risk of blood clots, strokes and damage to adjacent anatomical structures due to its unique design, which confines the delivery of energy to within the jaws of the ablation clamps and allows the surgeon to control the application of energy to the tissue targeted for ablation.

We cannot assure you that our system will receive FDA clearance or approval for the ablation of cardiac tissue or for the treatment of AF. If the lack of FDA clearance or approval were to prevent sales of our system, we would lose substantially all of our revenue and would require significant financing to conduct the necessary clinical trials and sustain our operations until sales could resume, if at all.

## **AtriCure Products**

The AtriCure bipolar ablation system consists of our ASU and a series of uniquely designed disposable Isolator ablation clamps. Our ASU is a compact power generator that uses our proprietary software and delivers bipolar radio-frequency energy. Based on our proprietary software, the energy delivered to the tissue varies depending on the thickness and type of tissue being ablated. Currently, we sell six different Isolator ablation clamps of various configurations and we generally lend our ASU to doctors and hospitals that purchase our disposable ablation clamps. All of our Isolator ablation clamps have jaws that are capable of compressing individual or multiple layers of tissue to direct and confine the treatment to the tissue targeted for ablation. We recently introduced two new Isolator endoscopic ablation clamps that are specifically designed for use in sole-therapy minimally invasive procedures. These ablation clamps can be used with our unique glide-path transfer guide and are designed to simplify our sole-therapy minimally invasive procedure, making it more adaptable to a broader number of surgeons and allowing surgeons the ability to perform a completely thorascopic (through small incisions in the chest) procedure. We released these two new ablation clamps in the first quarter of 2006 and anticipate releasing a version of these clamps during the third quarter of 2006 that may be used during open-heart procedures.

In addition to the AtriCure bipolar ablation system, we sell a pen-shaped ablation device known as the Isolator bipolar pen, which is complementary to our system and has been cleared by the FDA for the surgical ablation of cardiac tissue. This device is disposable and is powered by the same ASU that powers the AtriCure bipolar ablation system. Surgeons are using this device during sole-therapy minimally invasive procedures to both stimulate and ablate cardiac nerves in order to potentially increase procedure efficacy. We have also developed a switch box to be used with our pen device that is designed to enable surgeons to simply toggle back and forth between stimulation and ablation. Additionally, because of the device's slim, pen-shaped design, some

surgeons prefer using this device during open heart procedures either with our clamps or independently. We released the Isolator bipolar pen for sale in the third quarter of 2005.

We also sell the Wolf dissector, a product cleared by the FDA for the dissection of soft tissues during general, thoracic and certain other surgical procedures. The Wolf dissector was designed by Dr. Randall Wolf, who is a leader in the field of minimally invasive cardiothoracic surgery and one of our consultants. This dissection tool is used by surgeons to separate tissues surrounding the heart to provide access to key anatomical structures that are targeted for ablation during sole-therapy minimally invasive AF treatments. The Wolf dissector is a disposable handpiece that consists of a minimally invasive shaft with an articulating index finger-shaped tip that illuminates. The illuminated tip allows surgeons to more easily determine the movement, direction and position of the device during minimally invasive procedures.

We also distribute an ablation device that uses cryotherapy, or extreme cold, to ablate tissues. Some surgeons use this device in conjunction with our system to create lesions around heart valves as part of AF treatment.

We are developing the AtriCure Cosgrove-Gillinov Clip, which is designed to exclude the left atrial appendage, the small appendage that is attached to the left atrium, during open-heart surgical procedures and which may also be used to provide an option for high risk patients as a stand-alone left atrial appendage exclusion procedure following catheter ablation or pacemaker implantation. The left atrial appendage is considered by many physicians to be the source of blood clots which may cause a high percentage of AF-related strokes. We anticipate a limited release of the clip in the United States for use during open-heart procedures during the fourth quarter of 2006 subject to FDA review and clearance.

### ***Open-Heart Procedure***

During elective open-heart surgical procedures, such as bypass or valve surgery, cardiothoracic surgeons use the AtriCure bipolar ablation system to treat patients with AF. Surgeons report that ablation using our system generally adds approximately 20 minutes to an open-heart surgical procedure. Surgeons use our system to create sets of lesions that may vary depending on the length of time a patient has been diagnosed with AF and whether the patient's AF is intermittent or continuous. Patients who have been diagnosed with AF for a longer duration and have more continuous AF generally receive more ablation treatment than patients who have been diagnosed with AF for a shorter duration or who have intermittent AF. Ablation using our system during an open-heart procedure typically involves the following steps:

*Pulmonary Vein Isolation.* Regardless of the duration or type of AF, surgeons will create lesions in the tissue surrounding the pulmonary veins to create an electrical barrier between the pulmonary veins and the atrium, or upper chamber of the heart. In patients with intermittent AF, those lesions are often the extent of the treatment required to treat their AF. Cardiothoracic surgeons report that using our system enables them to safely, rapidly and reliably create lesions to achieve electrical isolation of the pulmonary veins from the atrium. In order to perform this procedure, surgeons position the jaws of our Isolator ablation clamps on the cardiac tissue surrounding the pulmonary veins. The jaws are clamped and the system is activated. Seconds later, an audible tone alerts the surgeons that the tissue no longer conducts energy, indicating that the lesion has become transmural and that the pulmonary veins have been electrically isolated.

*Additional Lesions.* For those patients who have been diagnosed with AF for a longer period and have more continuous AF, doctors may determine that additional lesions may be required to treat their AF. In cases where patients require such additional lesions, surgeons may use our system and our Isolator bipolar pen to create lesions in the atrium that are intended to reproduce similar electrical barriers to those created by surgeons during the classic Maze procedure. As with pulmonary vein isolation, doctors report that each lesion generally takes only seconds to create using our system.

### ***Sole-Therapy Minimally Invasive Procedure***

For those patients with AF that do not require an open-heart surgical procedure, surgeons have used our system as a sole-therapy minimally invasive treatment for AF. Using minimally invasive surgical techniques without the need to place patients on a heart-lung bypass machine, our system is used to isolate the pulmonary veins to treat AF. One of the key potential advantages of our sole-therapy minimally invasive treatment is the removal or mechanical isolation of the left atrial appendage. This appendage is believed to be responsible for the majority of strokes associated with AF. In order to perform this minimally invasive treatment, surgeons insert a lighted scope and other instruments through small incisions in the patient's chest. Surgeons report that the entire procedure takes approximately two to three hours and that the typical recovery time is approximately three to four days.

### **Business Strategy**

Our mission is to expand the treatment options for those patients who suffer from AF through the continued development of our proprietary technology platform and the education of medical professionals concerning our unique technologies. The key elements of our strategy include:

***Form Investigational Relationships with Key Opinion Leaders at Leading Institutions.*** We have formed investigational relationships with key opinion leaders at several leading cardiac care centers, such as the Cleveland Clinic, Washington University, the Medical City of Dallas and the University of Cincinnati. Several of these key opinion leaders have worked with us as consultants from our inception to develop our system. Additionally, they have evaluated our system and published peer-reviewed data that describes the use of our system as a treatment for AF. These opinion leaders continue to assist us with the design, clinical testing and evaluation of our products. To date, there have been approximately 15 peer-reviewed publications that describe our system's ability to create transmural lesions in order to treat AF. We believe that these publications, and the presentations given by key opinion leaders, have contributed to the adoption of our system as a standard treatment alternative for AF during open-heart surgical procedures.

***Provide Product Education.*** We have recruited and trained sales professionals who have strong backgrounds in the medical device field to effectively communicate to doctors the unique features and benefits of our technology as they relate to the ablation of soft tissue. Our highly trained sales professionals meet with doctors at leading institutions to provide education and technical training relating to our products. Additionally, we have provided educational grants to institutions that have facilitated the education of doctors concerning the treatment of AF, including the use of our system to treat AF. Through the education and publication process, we believe that awareness of our technology has grown, which will encourage doctors to use our products and refer patients for AF treatment using our system.

***Introduce and Expand Adoption of Our Sole-Therapy Minimally Invasive Procedure.*** There is currently no widely adopted sole-therapy treatment to cure AF. Currently, investigators are collecting clinical data, including data relating to safety and efficacy, to evaluate our system as a sole-therapy minimally invasive AF treatment. The encouraging results from a 27-patient study conducted by Dr. Wolf at the University of Cincinnati were used as a basis for our January 2005 investigational device exemption, or IDE, submission to the FDA requesting approval to conduct a study to demonstrate the feasibility of using our system as a sole-therapy minimally invasive AF treatment. The University of Cincinnati has initiated an internal review to validate the data from this study and we cannot assure you that this data will be validated. In July 2005, the FDA approved our IDE to conduct a feasibility study, known as RESTORE-SR II. This feasibility study, if successful, would likely be followed by a larger scale pivotal trial. The successful completion of our feasibility study will be the first step in obtaining FDA approval for use of our system as a sole-therapy minimally invasive AF treatment. We have modified our Isolator ablation clamps and developed other products to enable surgeons to ablate tissues through this minimally invasive approach. As of December 31, 2005, approximately 55 institutions were using our system during sole-therapy minimally invasive procedures to treat AF.

***New Product Innovation.*** Prominent medical journals, which contain articles that were written in part by leading cardiothoracic surgeons who are consultants to us, describe how cardiothoracic surgeons have used our

system to safely, rapidly and reliably create transmural lesions when treating AF. We believe that our system is a premier product that can be adapted for a variety of applications where surgeons need to create transmural lesions in soft tissues. We are expanding our technology platform to increase our market for products being used during open-heart surgical procedures. For example, we plan to investigate the use of our technologies in patients who have no history of AF yet are undergoing open-heart surgery and may be predisposed for developing AF, including patients at risk of developing post-operative AF, a temporary complication associated with cardiac surgery. We intend to leverage our leadership position in open-heart surgical ablation and expand our technology platform to provide a widely adopted solution for a sole-therapy minimally invasive AF treatment. In addition, we are currently developing the AtriCure Cosgrove-Gillinov Clip, a product that is designed to enable surgeons to mechanically isolate the left atrial appendage, which is believed to be responsible for the majority of AF-related strokes. We believe that the successful development of this clip device will add to the demand for surgical AF treatment by offering patients a one-step solution to AF treatment and left atrial appendage exclusion. Additionally, we are pursuing business development opportunities that will expand our technologies and capabilities to provide additional solutions for the treatment of AF.

### **Clinical Trials**

We are currently conducting an FDA-approved clinical trial, known as the RESTORE-SR trial, to evaluate the safety and efficacy of the AtriCure bipolar ablation system in treating AF during certain elective open-heart surgical procedures. As of February 28, 2006, we have enrolled approximately 12.8% of the patients required for this multicenter, 226-patient clinical trial. If the clinical trial is successful, we anticipate filing a PMA in 2008, which if approved by the FDA would allow us to market our system as an AF treatment during open-heart surgical procedures.

In July 2005, the FDA approved our IDE, which allows a non-FDA approved device to be used in clinical studies undertaken to develop safety and effectiveness data for that device, to conduct a clinical study to evaluate the feasibility of our system for the sole-therapy minimally invasive treatment of AF. The FDA has allowed us to begin our clinical study, known as RESTORE-SR II, which is expected to enroll a total of 25 patients at 5 leading US centers. A total of 17 patients have been treated in the study as of March 2, 2006 and we anticipate that enrollment and treatment of all 25 patients will be completed during the second quarter of 2006. If this feasibility study is successful, we plan to request that the FDA permit us to conduct a pivotal clinical trial to demonstrate the safety and efficacy of the AtriCure bipolar ablation system in treating AF as a sole-therapy minimally invasive approach. Each clinical study that we intend to complete will require a separate IDE or an amendment to an existing IDE. There is a 30-day time period for the FDA to act on an IDE or an amendment to an IDE and the FDA typically requests additional information prior to granting approval for a study to proceed. We generally expect that it will take several months after we file an IDE or an IDE amendment to obtain FDA approval.

### **Regulatory Clearances**

In August 2001, the FDA granted us 510(k) clearance to market the AtriCure bipolar ablation system for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures. We have not received FDA clearance or approval to promote our system for the ablation of cardiac tissue or for the use of our system in the treatment of AF. In December 2004, we submitted a 510(k) notification to obtain clearance for use of our system for the ablation of cardiac tissue, which had previously been sought by us in 2002 and 2003. In June 2005, the FDA denied that 510(k) clearance, finding that our system was not substantially equivalent to the already cleared predicate devices relied on in our 510(k) notice. The FDA also noted in its letter that our system has been reclassified as a Class III device. This means that we would now be required to obtain a PMA prior to the promotion of our system for the ablation of cardiac tissue. We may appeal the FDA's decision, but we cannot assure you that the FDA would reverse its decision. If that appeal is not successful, we would not intend to pursue a PMA for the ablation of cardiac tissue using our system and would instead pursue only the PMA for use of our system to treat AF.

In July 2004, the FDA granted us clearance to market our Wolf dissector for its intended use of dissection of soft tissues during general thoracic and certain other surgical procedures.

In June 2005, the FDA granted us 510(k) clearance to market our Isolator bipolar pen for its intended use of ablation of cardiac tissue during cardiac surgery.

In October 2005, the FDA granted us 510(k) clearance to market our newly designed Isolator endoscopic ablation clamps and the Glide-path transfer guide for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures.

We anticipate filing a 510(k) application in the second quarter of 2006 for the AtriCure Cosgrove-Gillinov Clip for an indication that includes left atrial appendage exclusion. We anticipate a limited release of the clip in the United States for use during open-heart procedures during the fourth quarter of 2006, subject to FDA review and clearance.

We received our original CE Mark approval for the AtriCure bipolar ablation system in July 2002, which allows us to market and sell the AtriCure bipolar ablation system throughout the European Union for the same uses for which it may currently be marketed in the United States. We have also received certifications to market and sell our system in several other foreign markets, including Canada, Japan, China, Brazil, Colombia, and Argentina. Additionally, we have begun the process of registration in Mexico and Australia where we expect approval for commercialization in these markets during 2006 and we are actively pursuing registration in other countries outside of the United States.

We received our original CE Mark approval for the Wolf dissector in February 2005, which allows us to market and sell the Wolf dissector throughout the European Union for the same uses for which it may currently be marketed in the United States. In October 2005, we also received approvals to market and sell the Wolf dissector in Japan and China. Additionally, we have begun the process of registration in Australia and Mexico where we expect approval for commercialization in these markets during 2006.

We received our original CE Mark approval for the Isolator bipolar pen in July 2005, which allows us to market and sell the Isolator bipolar pen throughout the European Union. We have also received approvals to market and sell the Isolator bipolar pen in Canada and China. Additionally, we have begun the process of registration in Australia, Mexico and Japan where we expect approval for commercialization in these markets during 2006-2007.

### **Sales, Marketing and Medical Education**

Our sales and marketing efforts focus on educating doctors concerning our unique technologies and the benefits of the AtriCure bipolar ablation system. We do not market or promote our system for the treatment of AF or the ablation of cardiac tissue. Our sales personnel visit cardiothoracic surgeons, electrophysiologists and other doctors to discuss the general attributes of our system, and they also promote our pen device for the surgical ablation of cardiac tissue and the Wolf dissector for the dissection of soft tissues during general, thoracic and certain other surgical procedures. We train our sales force on the use of our system to treat AF so that they are able to respond to unsolicited requests from doctors for information on the use of our system for the treatment of AF. In addition, medically trained clinical applications specialists attend surgical procedures to discuss the general aspects of our system and respond in a non-promotional manner to unsolicited requests for information on the use of our system for the treatment of AF. We have entered into consulting agreements with leading scientists, cardiothoracic surgeons and electrophysiologists who assist us with the design, clinical testing and evaluation of our products, educate doctors on the use of our technologies and provide advice concerning regulatory submissions. We work closely with these thought leaders to understand unmet needs and emerging applications in the treatment of AF. We also provide educational grants to several leading cardiac care centers.



These institutions have used these grants to sponsor independent activities to evaluate the effectiveness of our system and our technology, which has increased the number of peer-reviewed publications that cite the use of our system. These grants have also been used by these institutions to sponsor educational programs relating to AF, including programs which focus on the surgical treatment of AF using our system. We do provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians in the use of our system in the treatment of AF.

We have formed a healthcare compliance committee in support of our ongoing efforts to improve compliance with applicable federal and state healthcare laws and regulations. This committee has instituted standard operating procedures relating to our marketing and promotional activities, grant review and funding procedures, and the training and education of our sales force. We have modified our training and educational programs to include training on federal and state requirements for marketing medical devices, and we have revised and maintain continuous oversight of our grant application and funding procedures and requirements.

Our sales team is led by a vice president of sales and five sales directors. As of December 31, 2005, our sales force had a total of approximately 44 employees, including 25 full-time regional sales representatives and one independent manufacturers' representative in the United States. We select our sales personnel based on their expertise in the medical device field, sales experience, reputation in the medical device industry, and their knowledge of our products and technologies. We believe at this time that our sales organization is appropriately sized and do not anticipate significant increases in the foreseeable future.

We market and sell our products in selected markets outside of the United States through independent distributors. During 2005, sales outside of the United States accounted for approximately 8.7% of our total revenue. We have a network of distributors outside of the United States who currently market and sell our products in Asia, Europe, the Middle East and South America. We continue to expand our presence in markets outside of the United States, including our entry into China, Japan, Canada, Brazil, Colombia, and Argentina and planned sales to Mexico and Australia in 2006. See "Risk Factors—Risks Relating To Our Business—We sell the AtriCure bipolar ablation system outside of the United States and are subject to various risks relating to international operations, which could harm our international revenue and profitability."

We have one reporting segment. For information regarding revenue from customers, operating losses and total assets for each of our last three fiscal years, please refer to our consolidated financial statements, which are included in Item 8 of this Form 10-K.

### **Seasonality**

During the third quarter, we experience a decline in sales that we attribute to the elective nature of the procedures in which our products are typically used, which we believe arises from fewer people choosing to undergo elective procedures during the summer months.

### **Competition**

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of our competitors have significantly greater financial and human resources than we do and have established reputations with our target customers, as well as worldwide distribution channels that are more established and developed than ours. Our primary competitors include Guidant Corp., Medtronic, Inc., St. Jude Medical Inc., Boston Scientific Corp., Edwards Lifesciences Corp. and CryoCath Technologies Inc. As of December 31, 2005, no company had received FDA approval or clearance to market an ablation system for use as a treatment for AF. However, our competitors have FDA clearance to market their non-clamp products that ablate cardiac tissue and we market our Isolator bipolar pen that is also cleared to ablate cardiac tissue. We and our competitors provide products that have been adopted by doctors for the off-label treatment of AF.

We and many of our competitors have developed surgical ablation devices that have been used to treat AF during open-heart surgical procedures. We and these competitors utilize a variety of different technologies as energy sources for the ablation devices, including laser technology, microwave, cryotherapy, high-intensity focused ultrasound, and radio frequency technologies. Each of these companies is also currently working with its core technology to develop devices that can be used as a sole-therapy minimally invasive AF treatment.

Some of our competitors offer catheter-based treatments, including Biosense Webster, Inc., EP Technologies, St. Jude Medical, Inc., and Cardima, Inc. These companies sell products that are used by doctors to treat the population of patients that have AF but are not candidates for open-heart surgery, which is the same group of patients that we believe would most benefit from sole-therapy minimally invasive AF treatments using the AtriCure bipolar ablation system. Some of these catheter-based treatments already have FDA clearance or approval for cardiac use, including the treatment of certain arrhythmias, although none has approval for the treatment of AF.

We believe that we compete favorably against companies that have products that are currently being used for the surgical treatment of AF, particularly in the market for devices that are being used for the treatment of AF as a sole-therapy minimally invasive procedure, although we cannot assume that we will be able to continue to do so in the future or that new devices that perform better than our system will not be introduced. We also believe that our system competes favorably when compared to catheter-based treatments.

Because of the size of the AF market and the unmet need for an AF cure, competitors have and will continue to dedicate significant resources to aggressively market their products. New product developments that could compete with us more effectively are likely because the surgical AF treatment market is characterized by extensive research efforts and technological progress.

Competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than our system. To compete effectively, we have to demonstrate that our system is an attractive alternative to other treatments by differentiating our products on the basis of safety, efficacy, performance, ease of use, brand and name recognition, reputation, service and price. We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. We expect that competitive pressures may result in price reductions and reduced margins over time for our products. Our system may be rendered obsolete or uneconomical by technological advances developed by one or more of our competitors.

### **Third-Party Reimbursement**

Payment for patient care in the United States is generally made by third-party payors. These payors include private insurers and government insurance programs, such as Medicare or Medicaid. The Medicare program, the largest single payor in the United States, is a federal health benefit program administered by the Centers for Medicare and Medicaid Services, or CMS, and covers certain medical care items and services for eligible elderly, blind, and disabled individuals. The coverage under Part A of the Medicare program includes hospital and other institutional services, while Part B of Medicare includes doctors' services. Because Medicare beneficiaries comprise a large percentage of the populations for which our system is used, and private insurers may follow the coverage and payment policies for Medicare, Medicare's coverage and payment policies are significant to our operation.

The original fee-for-service portion of the Medicare Part A program pays hospitals for inpatient services under a prospective payment system, which provides for a pre-determined payment amount based on a patient's discharge diagnosis. Discharge diagnoses are grouped into Diagnosis Related Groups, or DRGs, which determine the payment amount for the inpatient hospital services. The payment amount is intended to reflect the costs of admitting and treating the patient. These payment amounts differ for each inpatient discharge. Currently, hospitals do not receive any additional payments from the fee-for-service Medicare program for the cost of

inpatient treatment of AF as part of an open-heart procedure. In these cases, the use of an ablation device to provide the AF treatment is included in the payment for the open-heart procedure. Sole-therapy minimally invasive AF treatment also qualifies for payment from the fee-for-service Medicare Part A program, which allows the hospital to receive payment for this type of AF treatment. The Medicare program has adopted specific hospital inpatient treatment codes describing AF treatment by ablation in sole-therapy and open-heart procedures such as those provided through the use of the AtriCure bipolar ablation system. However, the existing Medicare inpatient coverage, coding or payment policies are subject to change by CMS. As a result, the continuance of current coverage, coding or payment determinations cannot be guaranteed, and any change may have an adverse impact on our operations.

Doctors are reimbursed for their services separately under the Medicare Part B physician fee schedule. Doctors performing AF treatment during an open-heart procedure receive a payment that reflects several factors, including the time and complexity of the AF treatment. Doctors who perform a sole-therapy minimally invasive procedure receive payment that is comparable to the reimbursement paid to doctors for performing an open-heart surgical procedure.

Claims for procedures using our system are typically submitted by the doctor to Medicare Part B carriers (typically insurance companies under contract to CMS) or other health insurers using established billing codes, including the Current Procedural Terminology, or CPT, billing codes maintained by the American Medical Association. The billing codes identify the procedure or procedures performed and are relied upon to determine third-party payor amounts. Existing CPT billing codes describe surgical cardiac ablation procedures. Market acceptance of our products is dependent on coverage and adequate payment levels from such payors.

Currently, we believe that the AF treatment reimbursement rates are adequate for doctors and hospitals to cover the use of our system for the treatment of AF. In 2005, we estimate that the national Medicare payment rate for an open-heart procedure, whether or not the AF treatment is included, was approximately \$24,000 to \$45,000, depending on the type of open-heart procedure being performed, the geographic region and the type of facility. We estimate that the national medical hospital rates for AF treatment performed as a sole-therapy minimally invasive treatment were approximately \$24,000 to \$49,000, depending on the geographic region and type of facility. The cost of AF treatment performed during open-heart surgical procedures is not reimbursed separately by the Medicare program and the reimbursement rules for open-heart surgical procedures include supplies, including the use of an ablation device, but exclude doctor's fees for these procedures, which payors remit to doctors in addition to the amounts paid to hospitals for AF treatment procedures. Payment rates of other third-party payors may be the same as or higher or lower than Medicare rates, depending on their particular reimbursement methodology.

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines, and those payors may reimburse only a portion of the cost of AF treatment, or not at all.

The AtriCure bipolar ablation system has received FDA clearance for the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures. However, because the FDA does not regulate the practice of medicine, doctors may use the AtriCure bipolar ablation system in other circumstances where they deem it medically appropriate, even though the FDA has not approved or cleared our system for that indication. In these circumstances, some government or private payors, including some Medicare carriers, may make coverage and payment determinations on a case-by-case basis. Additionally, some government or private payors may deem the treatment of AF using the AtriCure bipolar ablation system for indications not approved or cleared by the FDA to be experimental or not medically necessary and, as such, may not provide coverage or payment.

## **Acquisition of Enable Medical Corporation**

Contemporaneously with the closing of the initial public offering of our common stock on August 10, 2005, we acquired Enable Medical Corporation, the manufacturer of our disposable Isolator ablation clamps, which are an essential component of the AtriCure bipolar ablation system, for an aggregate purchase price of approximately \$7 million. In addition, under the terms of the merger agreement that we entered into with Enable, if certain Enable assets unrelated to the AtriCure bipolar ablation system are sold prior to the third anniversary of the closing of our acquisition of Enable, we will be required to pay the former shareholders of Enable 50% of the consideration from that sale that is in excess of \$1 million, subject to a maximum payment to the Enable shareholders of \$2 million.

Prior to our acquisition, Enable was comprised of two business units, Enable Surgical Products and Enable Design and Manufacturing. The Surgical Products unit was engaged in the research and development of radio-frequency energy-based surgical products. The Surgical Products unit distributed a line of bipolar scissors in the United States, Europe, and Asia and had a portfolio of radio-frequency technologies covered by U.S. and European patents that were being considered for licensing or commercialization. The Design and Manufacturing unit provided contract design, research and development and manufacturing services to us and other medical device companies.

## **Government Regulation**

The AtriCure bipolar ablation system is a medical device subject to regulation by the FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. We currently market our system in the United States under a 510(k) clearance for the ablation and coagulation of soft tissues during general, ear, nose and throat, thoracic, gynecologic and urologic surgical procedures. Currently, our system may not be marketed for ablation of cardiac tissue or for the treatment of AF without obtaining additional clearances and approvals from the FDA.

The FDA requires that premarket approval, or PMA, be obtained for a device before it can be marketed for the treatment of AF. A PMA will require clinical data supporting the safe and effective use of the device in the treatment of AF. In December 2003, we received an investigational device exemption, or IDE, from the FDA to conduct clinical trials of our system in a prospective, multi-center trial, known as the RESTORE-SR trial, to evaluate the safety and efficacy of our system for the treatment of AF during open-heart surgery. In addition, in July 2005, we received FDA approval to conduct a clinical study to demonstrate the feasibility of using the AtriCure bipolar system for the sole-therapy minimally invasive treatment of AF that also includes removal of a portion of the heart called the left atrial appendage. If this feasibility study is successful, we would need to conduct a pivotal trial to support marketing authorization. We cannot assure you that we will successfully complete RESTORE-SR or RESTORE-SR II, receive approval for any additional clinical trials or submit and obtain approval for our system for use in treating AF.

The Wolf dissector, the Isolator bipolar pen, and the AtriCure Cosgrove-Gillinov Clip are also medical devices subject to regulation by the FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. We currently market the Wolf dissector in the United States under a 510(k) clearance for use in the dissection of soft tissues during general, ear, nose and throat, thoracic, urological and gynecological surgical procedures and we market our pen device in the United States under a 510(k) clearance for use in the surgical ablation of cardiac tissue. We anticipate filing a 510(k) application in the second quarter of 2006 for the AtriCure Cosgrove-Gillinov Clip for an indication that includes left atrial appendage exclusion. We are not currently seeking any further approvals or clearances from the FDA relating to these devices.

FDA regulations govern nearly all of the activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities that the FDA regulates include the following:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- pre-clinical testing in animals and in the laboratory;
- clinical investigations in humans;
- premarketing clearance or approval;
- record keeping and document retention procedures;
- advertising and promotion;
- product marketing, sales and distribution;
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, device malfunctions or other adverse events; and
- corrective actions, removals and recalls.

***FDA's Premarket Clearance and Approval Requirements.*** Unless an exemption applies, each medical device distributed commercially in the United States will require either prior 510(k) clearance or a PMA from the FDA. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree of risk associated with each medical device. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a 510(k) notification requesting clearance to commercially distribute the device. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, or predicate device, are placed in Class III, requiring submission of a PMA supported by clinical trial data.

The FDA has previously classified the AtriCure bipolar ablation system as a Class II device and has granted us 510(k) clearance to market this product for the ablation and coagulation of soft tissues during certain surgical procedures. The FDA denied 510(k) clearance of our system for the ablation of cardiac tissue because the FDA determined that our system is not substantially equivalent to an already cleared device. The FDA has taken a position that no radio-frequency surgical clamps are general cardiac tools because radio-frequency surgical clamps are specifically designed and intended for use in surgical ablation to treat AF. As such, no radio-frequency surgical clamps from any medical device company, including ours, have been cleared for cardiac ablation to date. The FDA has reclassified our system as a Class III device, which means that we would now be required to obtain a PMA prior to any promotion of our system for the ablation of cardiac tissue. We may appeal the FDA's decision, but if that appeal is not successful, we would not intend to pursue a PMA for the ablation of cardiac tissue using our system and would instead pursue only the PMA for use of our system to treat AF. In order to market our system for the treatment of AF, the FDA requires that we seek approval through submission to the FDA of a PMA. Submission of a PMA is a much more demanding process than the 510(k) notification process. Both 510(k)s and PMAs must now be submitted with a potentially substantial user fee payment to the FDA, although certain exemptions and waivers can apply, including certain exemptions and waivers for small businesses.

***510(k) Clearance Pathway.*** When 510(k) clearance is required, we must submit a notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA. The FDA is required to respond to a 510(k) notification

within 90 days of submission, but the response may be a request for additional information or data, including clinical data. As a practical matter, 510(k) clearance often takes significantly longer than 90 days, and may take up to one year or more. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the device is automatically placed into Class III, requiring the submission of a PMA. Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, in connection with safety and effectiveness, approval of a PMA. The FDA requires every manufacturer to make the determination regarding a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We have made modifications to elements of our system, but we do not believe that such modifications will require us to seek additional 510(k) clearance. The FDA may not agree with our decisions regarding whether new 510(k) clearances are required. If the FDA disagrees with us and requires us to submit a new 510(k) or PMA, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

***Premarket Approval Pathway.*** A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. The PMA process is much more demanding than the 510(k) notification process. A PMA must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA is submitted and the FDA has determined that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for filing. The FDA has 180 days to review an "accepted" PMA, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMAs or PMA supplements are required for significant modification to the device, including indicated use, manufacturing process, labeling and design of a device that is approved through the premarket approval process. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

***Clinical Trials.*** Clinical trials are generally required to support a PMA and are sometimes required for 510(k) clearance. In the United States, clinical trials for a significant risk device require the prior submission of an application for an IDE to the FDA for approval. An IDE amendment must also be submitted before initiating a new clinical study under an existing IDE, such as initiating a pivotal trial following the conclusion of a feasibility trial. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The animal and laboratory testing must meet the FDA's good laboratory practice requirements.

The IDE and any IDE supplement for a new trial must be approved in advance by the FDA for a specific number of patients. Clinical trials for significant risk devices may not begin until the IDE application or IDE supplement is approved by the FDA and the appropriate institutional review boards, or IRBs, overseeing the welfare of the research subjects and responsible for that particular clinical trial. If the product is considered a non-significant risk device under FDA regulations, only the patients' informed consent and IRB approval are

required. Under its regulations, the agency responds to an IDE or an IDE amendment for a new trial within 30 days. The FDA may approve the IDE or amendment, grant an approval with certain conditions, or identify deficiencies and request additional information. It is common for the FDA to require additional information before approving an IDE or amendment for a new trial, and thus final FDA approval on a submission may extend beyond the initial 30 days. The FDA may also require that a small-scale feasibility study be conducted before a pivotal trial may commence. In a feasibility trial, the FDA limits the number of patients, sites and investigators that may participate. Feasibility trials are typically structured to obtain information on safety and to help determine how large a pivotal trial should be to obtain statistically significant results.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

**Educational Grants.** The FDA permits a device manufacturer to provide financial support, including support by way of grants, to third-parties for the purpose of conducting medical educational activities. If these funded activities are considered by the FDA to be independent of the manufacturer, then the activities fall outside the restrictions on off-label promotion to which the manufacturer is subject.

The FDA considers several factors in determining whether an educational event or activity is independent from the substantive influence of the device manufacturer and therefore nonpromotional, including the following:

- whether the intent of the funded activity is to present clearly defined educational content, free from commercial influence or bias;
- whether the third-party grant recipient and not the manufacturer has maintained control over selecting the faculty, speakers, audience, activity content and materials;
- whether the program focuses on a single product of the manufacturer without a discussion of other relevant existing treatment options;
- whether there was meaningful disclosure to the audience, at the time of the program, regarding the manufacturer's funding of the program, any significant relationships between the provider, presenters, or speakers and the supporting manufacturer, and whether any unapproved uses will be discussed; and
- whether there are legal, business, or other relationships between the supporting manufacturer and the provider or its employees that could permit the supporting manufacturer to exert influence over the content of the program.

We believe that the activities we support pursuant to our educational grants program are in accordance with these criteria for independent educational activities.

**Pervasive and Continuing Regulation.** There are numerous regulatory requirements governing the approval and marketing of a product. These include:

- FDA's Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting, or MDR, regulations, which require that manufacturers comply with reporting requirements of the FDA and report if their device may have caused or contributed to an adverse event, a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- notices of correction or removal and recall regulations.

MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to an adverse event, a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. As of March 15, 2006, we have notified the FDA of thirteen reports of complications during procedures utilizing our products. Of these MDRs, one relates to our first generation dissection tool, the PVI-7, which we no longer manufacture or sell, ten relate to our Isolator bipolar ablation clamps and two relate to the Wolf dissector. There have also been other incidents, including patient deaths, that have occurred during open-heart and sole-therapy minimally invasive procedures using our system that we have not, and believe were not required to be, reported to the FDA, because we determined that these incidents were not related to the use of our system.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

We have registered with the FDA as a medical device manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

***Fraud, Abuse and False Claims.*** We are directly and indirectly subject to various federal and state laws governing our relationship with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from



knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Services, or OIG, has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

The Federal False Claims Act imposes civil liability on any person or entity who submits, or causes the submission of a false or fraudulent claim to the United States Government. Damages under the Federal False Claims Act can be significant and consist of the imposition of fines and penalties. The Federal False Claims Act also allows a private individual or entity with knowledge of past or present fraud on the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice on behalf of the government has successfully enforced the Federal False Claims Act against pharmaceutical manufacturers. The federal suit has alleged that pharmaceutical manufacturers whose marketing and promotional practices were found to have included the off-label promotion of drugs or the payment of prohibited kickbacks to doctors violated the FCA on the grounds that these prohibited activities resulted in the submission of claims to federal and state healthcare entitlement programs such as Medicaid, resulting in the payment of claims by Medicaid for the off-label use of the drug which was not a use of the drug otherwise covered by Medicaid. Such manufacturers have entered into settlements with the federal government under which they paid amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions.

The federal authorities, and state equivalents, may likewise seek to enforce the False Claims Act against medical device manufacturers. We believe that our marketing practices are not in violation of the Federal False Claims Act or state equivalents, but we cannot assure you that the federal authorities will not take action against us and, if such action were successful, we could be required to pay significant fines and penalties and change our marketing practices. Such enforcement could have a significant adverse effect on our ability to operate.

We engage in a variety of activities that are subject to these laws and that have come under particular scrutiny in recent years by federal and state regulators and law enforcement entities. These activities have included, consulting arrangements with cardiothoracic surgeons, grants for training and other education, grants for research, and other interactions with doctors.

AdvaMed is one of the primary voluntary United States trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with regulatory matters.

We have adopted the AdvaMed Code and incorporated its principles in our standard operating procedures, sales force training programs, and relationships with doctors. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of

training, education and scientific research, and limit payments between manufacturers and healthcare professionals to payment of fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. We have incorporated these principles into our relationships with healthcare professionals under our consulting agreements, payment of travel and lodging expenses, grant making procedures and sponsorship of third-party conferences. In addition, we have conducted training sessions on these principles.

***Regulation Outside of the United States.*** Sales of medical devices outside of the United States are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different.

The primary regulatory body in Europe is that of the European Union, which has adopted numerous directives and has promulgated voluntary standards regulating the design, manufacture and labeling of and clinical trials and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. The method for assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required for a manufacturer to commercially distribute the product throughout these countries. International Standards Organization, or ISO 9001 and ISO 13845 certifications are voluntary standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. We have the authorization to affix the CE Mark to our system and to commercialize our system in the European Union for the ablation and coagulation of soft tissues during general, ear nose and throat, thoracic, gynecologic and urologic surgical procedures.

## **Intellectual Property**

Protection of our intellectual property is a strategic priority for our business, and we rely on a combination of patent, copyright, trademark and trade secret laws to protect our interests. Our ability to protect and use our intellectual property rights in the continued development and commercialization of our technologies and products, operate without infringing the proprietary rights of others, and prevent others from infringing our proprietary rights is crucial to our continued success. We will be able to protect our products and technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, trademarks or copyrights or are effectively maintained as trade secrets, know-how or other proprietary information.

We seek patent protection relating to our system and other important technologies we develop in both the United States and in selected foreign countries. While we own much of our intellectual property, including patents, patent applications, trademarks, trade secrets, know-how and proprietary information, we also license patents and related technology of importance to commercialization of our products. For example, to continue developing and commercializing our current and future products, we may license intellectual property from commercial or academic entities to obtain the rights to technology that is required for our research, development and commercialization activities.

All of our employees and technical consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived in connection with their relationship with us. We cannot provide any assurance that employees and consultants will abide by the confidentiality or assignment terms of these

agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our system or obtain and use information that we regard as proprietary.

We devote significant resources to obtaining patents and other intellectual property and protecting our other proprietary information. We have already obtained patents or filed patent applications on a number of our technologies, including patents and patent applications relating to our bipolar ablation system and ancillary devices. If valid and enforceable, these patents may give us a means of blocking competitors from using infringing technology to compete directly with our products. We also have certain proprietary trade secrets that may not be patentable or for which we have chosen to maintain secrecy rather than file for patent protection. With respect to proprietary know-how that is not patentable, we have chosen to rely on trade secret protection and confidentiality agreements to protect our interests. As of December 31, 2005, we had eight issued United States patents that will expire in 2015, two that will expire in 2016, two that will expire in 2018, six that will expire in 2020 and three that will expire in 2021.

As of December 31, 2005, we had the following portfolio of 68 issued patents or patent applications covering our proprietary technologies and products, of which a total of 19 were acquired from Enable:

- 21 issued United States patents;
- 22 United States non-provisional patent applications;
- 3 United States provisional patent applications;
- 5 issued foreign patents;
- 9 pending foreign patent applications that are in various national stages of prosecution; and
- 8 pending foreign applications filed pursuant to the Patent Cooperation Treaty, or PCT, not at the national stage.

## **Manufacturing**

We manufacture the majority of the components that comprise the AtriCure bipolar ablation system. However, some of the components of our system, including our ASU, come from outside suppliers. We inspect, assemble, test and package our products in West Chester, Ohio and our products are sterilized by outside sterilization facilities.

Purchased components for our system are generally available from more than one supplier, with the exception of our ASU. Our ASU is a critical component of the AtriCure bipolar ablation system, and there are relatively few alternative sources of supply available. We do not carry a significant inventory of this component and obtaining a replacement supplier for the ASU, if required, may not be accomplished quickly or at all and could involve significant additional costs. With the exception of Stellartech Research Corporation, the supplier of our ASU, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies.

In June 2005, we entered into a manufacturing agreement with Stellartech whereby we agreed, among other things, to purchase, and Stellartech agreed to supply, the first 400 Ablation Sensing Units, or ASUs, that we require. As of December 31, 2005, we had fulfilled our obligation to purchase the first 400 ASUs from Stellartech and were required to purchase at least 75% of our ASU requirements from Stellartech until November 2007. We may, however, extinguish our obligation to purchase 75% of our ASU requirements from Stellartech by paying to Stellartech either a certain percentage of the gross margin Stellartech would have received if it had

manufactured the ASUs or a specified dollar amount. This agreement has an initial three-year term and renews for successive one-year periods, unless terminated. This agreement may be terminated by Stellartech for any reason upon six months' notice to us. We may terminate the agreement in the event the development agreement is terminated prior to expiration or after we have fulfilled the purchase requirements under the agreement. Under the terms of this agreement, we have certain indemnification obligations, including with respect to claims relating to intellectual property infringement, design defects and manufacturing defects. Any supply interruption or failure to obtain our ASU would limit our ability to sell our system and could have a material adverse effect on our business, financial condition and results of operations.

Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have not experienced significant delays in obtaining any of our components. There are no unique or proprietary processes required in manufacturing our components. We are under no contractual obligations that preclude us from developing products or sourcing components from new suppliers.

We and our component suppliers are required to manufacture our products in compliance with the FDA's QSR. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. The FDA enforces the QSR through periodic inspections that may be announced or unannounced and may include the manufacturing facilities of our subcontractors. Our failure or the failure of our component suppliers to maintain compliance with the QSR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would have a material adverse effect on our business. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We also could be subject to injunctions, product seizures, or civil or criminal penalties.

We regularly audit our suppliers for compliance with QSR, and applicable ISO standards. We have been an FDA-registered medical device manufacturer since November 2002. We obtained our CE Mark in June of 2002, and our quality systems and facility practices are certified to ISO 13485:2003; MDD 93/42/EEC, or CE Mark; and CMDCAS, or Canadian regulations. We believe that we are currently in good standing with the FDA and are subject to pre-announced inspections. Our current quality system is developed to comply with QSR and ISO standards. At the time of our acquisition of Enable, it advised us that it was in full compliance with ISO 9001:1994, and ISO 13485:2003 and it had undergone two full quality system audits and six surveillance audits by TUV America, Inc. Enable's most recent audit was in December 2004 and it was a full quality system audit. There were no major non-conformance issues and Enable had advised us that it was in substantial compliance with ISO 13485:2003 at the time of the acquisition.

We were inspected by the FDA in February 2003 as part of a not-for-cause, general QSR inspection. The FDA made no observations requiring our response. There were no findings that involved a material violation of regulatory requirements. Enable was inspected by the FDA in June 2000 as part of a not-for-cause, general QSR inspection. The FDA made five observations that did not require any response, but Enable provided the FDA with a response of corrective action. In December 2004, Stellartech, the manufacturer of our ASU, was inspected by the FDA as part of a not-for-cause, general QSR inspection. The FDA issued a notice with three observations requiring responses. Stellartech has addressed those observations and sent their responses to the FDA.

Enable had been registered with the Ohio Environmental Protection Agency, or Ohio EPA, as a small waste generator since 2001. The Ohio EPA audited Enable in March 2001 and made four observations. Enable performed corrective action and the Ohio EPA found all corrective actions taken to be effective.

We are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, controlled drug substances, safe working conditions, manufacturing practices, environmental protection and fire hazard control. We may incur significant costs to comply with those laws and regulations now or in the future, but we do not expect that such compliance will have a material impact on our business.

We are currently increasing our manufacturing capabilities as we increase commercialization efforts. Manufacturers can experience difficulties in significantly scaling up production capacities, which may include problems with capacity, production yields and quality control. If we are unable to manufacture our products to keep up with demand, we will not meet expectations for growth of our business.

## **Product Development**

Our product development group develops product enhancements and new products to address unmet procedural and market needs with the goal of increasing revenue. Our current product development activity includes projects extending and improving the existing Isolator product family, development of a new device platform, creation of new enabling devices such as new dissection, guidance and ablation tools and research into new technologies. Product extensions and improvements of the Isolator product family include software enhancements, cost savings and support for increased production capacity. Development of a new device platform includes implementation of a design to further refine the minimally invasive procedure, improve manufacturing efficiencies and create a platform for future feature implementation. Enabling devices are becoming an increasingly larger portion of our development portfolio and include the 2004 release of the Wolf dissector, the third quarter 2005 release of the Isolator bipolar pen and the first quarter 2006 release of our newly designed Isolator endoscopic ablation clamps, which include a glide-path transfer guide. New technology research includes development of devices for stroke prevention, including for the exclusion of the left atrial appendage, development of alternative complementary energy sources and development of additional tools.

In June 2005, we entered into a 19-month development agreement with Stellartech whereby Stellartech agreed to develop enhancements to the current ASU technology and granted us a license to use Stellartech's technology in the field of cardiac arrhythmia treatment. We agreed to pay Stellartech on an hourly basis, based on the types of services being performed. In addition, materials and components, out-of-pocket expenses and outside services will be billed to us at cost plus a specified percentage. We may terminate this agreement upon 30 days' notice and have no minimum payment obligations. Under the terms of this agreement, we have certain indemnification obligations to Stellartech relating to its performance of services under the agreement, except for Stellartech's breach, fraud, negligence or misconduct and infringement relating to intellectual property owned by Stellartech, for each of which it indemnifies us.

In July 2005, we entered into a development and license agreement with UST Inc., whereby UST agreed to design and develop a high intensity focused ultrasound, or HIFU, system to create certain types of lesions and granted us an exclusive, worldwide license to related technology. We believe that HIFU may be a valuable alternative source of energy for making certain kinds of lesions. We agreed to pay UST an initial development fee of \$375,000 and an additional development fee of \$966,000, payable in fourteen monthly installments. If UST has not completed its development services within fourteen months, we will be required to pay UST the direct costs incurred by it for the following six months in connection with continuing to render development services. We are also required to pay UST royalties of 4% of the net sales of the HIFU system, up to a maximum amount of \$15 million in royalties during the royalty term. In addition, we are required to make certain license and maintenance payments to UST for the sublicenses granted to us under the terms of this agreement. We may terminate this agreement at any time by giving notice to UST. UST may terminate this agreement if we fail to timely commercialize the HIFU system or if we fail to timely pursue FDA approval or clearance of the HIFU

system. Under the terms of this agreement, we have certain indemnification obligations to UST for our breach of this agreement. In order to commercialize this HIFU system, we may be required to license additional intellectual property from third parties. We cannot assure you that we will be able to license this technology on commercially reasonable terms, if it all.

The Cleveland Clinic Foundation and Case Western Reserve University and collaborating businesses, including us, received publicly announced grants from the State of Ohio for the creation of the Atrial Fibrillation Innovation Center. The grants are intended to enable the center to develop both surgical and non-invasive treatments to help prevent and potentially cure atrial fibrillation. While we have not yet executed final grant documents, we anticipate receiving from the grant approximately \$0.9 million for operating expenses and approximately \$2.4 million for capital expenses, each over a three-year period. Over the same three-year period, we anticipate being required by the grant terms to provide approximately \$7.7 million for operating expenses and approximately \$4.8 million for capital expenses at our facility, which amounts represent ordinary course expenditures that we would have otherwise anticipated making. Additionally, we may establish an office at the Cleveland Clinic staffed with our engineers.

In November 2003, we entered into a license and related agreements with the Cleveland Clinic and a third party engineering company for the development of a clip intended to exclude the left atrial appendage. Under this arrangement, we agreed to grant approximately 33,000 options to each of the Cleveland Clinic and the engineering company upon satisfaction of a milestone tied to the technical feasibility and commercial viability of the licensed intellectual property, which milestone we believe has been met, in addition to payment of royalties to each of the Cleveland Clinic and the engineering company equal to 2.5% of net sales of any commercialized products using the licensed technology. We are pursuing a series of pre-clinical studies which, if successful, are intended to support a 510(k) submission to the FDA in the second half of 2006 for a product using the licensed technology.

### **Consulting Relationships**

We have developed consulting relationships with a number of leading scientists and doctors to give our research and development team additional technical and creative breadth. We work closely with these thought leaders to understand unmet needs and emerging applications in the treatment of AF. We typically enter into a written agreement with the consultant pursuant to which the consultant is obligated to provide services such as advising us as to the design and development of our products and procedures, educating doctors on the FDA-cleared or approved use of our technologies, conducting clinical trials and providing supporting data for clinical trials and providing advice concerning grants and regulatory submissions. These agreements are for a term of one to three years. The agreements may be terminated by us or by the consultant upon 30 to 60 days' notice. We own the rights to any inventions or ideas made or conceived by our consultants during performance of the consulting services.

On November 21, 2005, we entered into a Royalty Agreement, effective as of October 1, 2005, with Randall K. Wolf, M.D., the co-inventor of the Wolf dissector. Pursuant to the terms of the Royalty Agreement, we will pay to Dr. Wolf royalties based on revenue from sales of the Wolf dissector and certain other inventions, improvements or ideas, at royalty rates which range from 1.5% to 15% of such revenue. During the term of the Royalty Agreement we are required to pay Dr. Wolf a minimum of \$50,000 in royalties per quarter and up to an aggregate of \$2,000,000 in royalties during the term of the Agreement. The Agreement terminates on December 31, 2009; however, we and Dr. Wolf each have the right at any time to terminate the Royalty Agreement immediately for cause.

Compensation, in both cash and stock, was made, in part, upon determination by us that services had been provided to our satisfaction. Fees paid to Dr. Wolf during 2005, including amounts paid to him under his Royalty Agreement, aggregated approximately \$223,000. Fees paid to other consultants during 2005 ranged from \$5,000 to \$60,000 for the year and were paid monthly, quarterly or on a per diem basis. Beginning in the fourth quarter of 2005, we entered into new agreements with most of our consultants that replaced their existing agreements.

These new agreements provided for payment of compensation in cash only and on a per diem basis, upon determination by us that services have been provided to our satisfaction. In addition, under agreements entered into prior to the fourth quarter of 2005, some of our consultants are entitled to receive stock options.

Upon presentation of appropriate documentation, reasonable travel and other expenses are also reimbursed. We do not expect or require the consultant to utilize or promote our products, and consultants are required to disclose their relationship with us as appropriate, such as when publishing an article in which our system is discussed. See “Risk Factors—Risks Relating To Our Business—We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our product for non-FDA-approved, or off-label, uses.”

## **Employees**

As of December 31, 2005, we had 160 full-time employees, including 42 in research and development, regulatory and clinical affairs, 56 in sales and marketing, 43 in operations, and 19 in administration. None of the employees was represented by a labor union or was covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be good. We also employ independent contractors to support our development, regulatory, sales, marketing and administrative activities.

## **Corporate History**

We were incorporated in the State of Delaware as AtriCure, Inc. on October 31, 2000 in connection with a spin-off transaction from Enable Medical Corporation, in which shares of our common stock were given to the Enable shareholders. The spin-off was intended to allow us to focus on the development of products designed to treat AF and to raise capital for that purpose, while Enable continued its broader research and manufacturing activities.

Upon the closing of the initial public offering of our common stock on August 10, 2005, we acquired Enable Medical Corporation, the manufacturer of our Isolator ablation clamps, which are an essential part of the AtriCure bipolar ablation system. Additionally, in December 2005, we formed AtriCure Europe, B.V., our wholly-owned subsidiary incorporated in the Netherlands.

## **Available Information**

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission, or SEC, including reports on the following forms: Form 10-K, Form 10-Q, Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning us may be accessed through the SEC’s website at <http://www.sec.gov>.

You may also find, free-of-charge, on our website at <http://www.atricure.com> electronic copies of our Form 10-K, Form 10-Qs, Form 8-Ks, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC. Our charter for our Audit, Compensation and Nominating and Corporate Governance Committees and our Code of Ethics are available on our website. In the event that we grant a waiver under our Code of Ethics, to any of our officers and directors, we will publish it on our website.

## **Item 1A. RISK FACTORS**

### **Risks Relating To Our Business**

**We expect to derive substantially all of our future revenue from sales of the AtriCure bipolar ablation system. If the AtriCure bipolar ablation system fails to gain or loses market acceptance for the treatment of AF, we may not generate sufficient revenue to continue our operations.**

Currently, our primary product line is the AtriCure bipolar ablation system, which we commercially introduced in 2002 in the United States and in 2003 outside of the United States. We expect that sales of the AtriCure bipolar ablation system will account for substantially all of our revenue for the foreseeable future and that our future revenue will depend on the acceptance by the medical community of the AtriCure bipolar ablation system as a standard treatment alternative for the surgical treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive treatment for AF.

Acceptance of our system for the treatment of AF is dependent upon, among other factors, the level of screening for AF and the awareness and education of the medical community about the surgical treatment of AF, in general, and the existence, effectiveness and safety of the AtriCure bipolar ablation system, in particular. Our system and the procedures involved with the treatment of AF using our system are relatively new. We cannot assure you that doctors will continue to use the AtriCure bipolar ablation system or that demand for the surgical treatment of AF will not decline or will increase as quickly as we expect.

We may not be able to maintain or increase market acceptance of the AtriCure bipolar ablation system for a number of additional reasons, including:

- our inability to promote our system for use on cardiac tissue or for the treatment of AF until we obtain additional FDA approvals or clearances;
- our inability to train doctors in the use of our system for the ablation of cardiac tissue or for the treatment of AF until we obtain additional FDA approvals or clearances;
- our inability to establish or sustain acceptance of our system within the medical community;
- liability risks for doctors and hospitals associated with the off-label use of our system and the use of new technologies or procedures;
- findings or perceptions relating to the safety or effectiveness of our system or the safety or effectiveness of the surgical treatment of AF;
- medical device reports to the FDA and foreign regulatory authorities, which are required in the event our products malfunction or cause or contribute to a death, serious injury or other adverse event;
- publicity concerning our system, competing products or the surgical treatment of AF;
- the cost of our system;
- the availability of alternative treatments or procedures that may be, or may be perceived as, more effective, safer, faster, easier to use or less costly than our system; and
- policies of healthcare payors with respect to coverage and reimbursement.

Since we do not believe that doctors are using the AtriCure bipolar ablation system for any purpose other than the surgical treatment of AF, if doctors do not use our system to treat AF, we would lose substantially all of our revenue.

**Use of the AtriCure bipolar ablation system as a sole-therapy minimally invasive treatment for AF, which is not currently an established market, represents our major growth opportunity. If this market does not develop or our system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenue.**

We believe that sole-therapy minimally invasive treatment for AF, which is not currently an established market, will ultimately represent the largest segment of the market for the surgical treatment of AF. If this market fails to develop, or if our system is not widely adopted for use in this market, it may adversely impact our ability to grow our revenue. In order to establish the sole-therapy minimally invasive AF treatment market, doctors treating patients with AF who would not otherwise require an open-heart surgical procedure must change their current practice of referring patients to cardiologists and electrophysiologists and instead refer these patients to



cardiothoracic surgeons for surgical AF treatment. Doctors may decide not to change their referral patterns for a variety of reasons including, for example, negative publicity relating to our ongoing clinical studies, including publicity focusing on the doctors and institutions carrying out such clinical studies, that limited clinical data is available relating to the safety and effectiveness of our system, that only a limited number of procedures have been performed using our system, that clinical testing of our system is in the feasibility stage, that doctors who refer their patients to cardiothoracic surgeons may risk losing their patients and that doctors may prefer to treat patients using drugs or catheter-based ablation. If doctors do not refer their patients to cardiothoracic surgeons for surgical AF treatment, we will not be able to establish a market for the use of our system for the sole-therapy minimally invasive treatment of AF, and our future growth and revenue will suffer.

**The failure to educate or train a sufficient number of doctors in the use of the AtriCure bipolar ablation system could reduce the market acceptance of our system and reduce our revenue.**

It is critical to the success of our sales efforts to ensure that there are a sufficient number of doctors familiar with, trained on and proficient in the use of our system. While we educate and train doctors as to the skills involved in the proper use of our system and technology, we cannot educate or train them to use our system for the ablation of cardiac tissue or the surgical treatment of AF unless and until we obtain additional FDA approvals or clearances. Currently, doctors learn to use our system for the treatment of AF through independent training programs provided by hospitals and universities and through independent peer-to-peer training among doctors. We provide research and educational grants to institutions, some of which are used to fund programs to teach the procedures involved in the surgical treatment of AF, including the use of our system for such treatment. However, while we make doctors generally aware of these programs, these institutions determine the faculty and the content of the programs. We also rely on doctors to independently inform their colleagues about these programs. We cannot assure you that a sufficient number of doctors will become aware of training programs or that doctors will dedicate the time, funds and energy necessary for adequate training in the use of our system.

**Unless we obtain additional FDA approvals or clearances, we will not be able to promote the AtriCure bipolar ablation system to ablate cardiac tissue or to treat AF and our ability to maintain and grow our business could be harmed.**

Generally, a medical device company must first obtain either FDA clearance through the submission to the FDA of a 510(k) notification or FDA approval through the submission of a pre-market approval application, or PMA, before a company may market a medical device in the United States. Certain modifications to a previously marketed device, including a proposed new use or new indication for the device, also require the submission to the FDA of either a 510(k) or PMA before such device with the modifications may be marketed. The process of obtaining these clearances and approvals can be lengthy and expensive. The PMA process is more costly, lengthy and uncertain than the 510(k) process and requires that the device be found to be safe and effective and must be supported by extensive data, including data from preclinical studies and human clinical trials. Though less likely, a 510(k) application may require human clinical trials as well. Because we cannot assure you that any new products, or any product enhancements, that we develop will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancement may occur.

We have not received FDA clearance or approval to promote our system for the ablation of cardiac tissue or for the use of our system in the treatment of AF. In December 2004, we submitted a 510(k) notification to obtain clearance for use of our system for the ablation of cardiac tissue, which had previously been sought by us and denied in 2002 and 2003. In June 2005, the FDA denied 510(k) clearance, finding that our system was not substantially equivalent to the already cleared predicate devices relied on in our 510(k) notice. The FDA also noted in its letter that our system has been reclassified as a Class III device. This means that we would now be required to obtain a full PMA, rather than a 510(k), in order to gain FDA approval of our system for the ablation of cardiac tissue. We may appeal the FDA's decision, but we cannot assure you that the FDA would agree to reverse its decision. If that appeal is not successful, we would not intend to pursue a PMA for the ablation of cardiac tissue using our system. Whether or not the FDA provides clearance for the use of the AtriCure bipolar ablation system to ablate cardiac tissue, we will need to obtain separate approvals from the FDA for use of the

AtriCure bipolar ablation system in the treatment of AF as part of an open-heart procedure and as a sole-therapy minimally invasive procedure through the submission of separate PMAs to the FDA.

Unless and until we obtain FDA clearance or approval for the use of our system for the ablation of cardiac tissue or for the treatment of AF, we and others acting on our behalf may not promote our system for such uses, make any claim that our system is safe and effective for such uses, or proactively discuss or provide information on the use of our system in connection with such uses. These limitations put us at a disadvantage relative to our competitors who have received clearance or approval to market their products for the ablation of cardiac tissue.

We cannot assure you that future clearances or approvals of the AtriCure bipolar ablation system will be granted or that current or future clearances or approvals of the AtriCure bipolar ablation system will not be withdrawn. Failure to obtain a clearance or approval or loss of an existing clearance or approval, could hurt our ability to maintain and grow our business.

**Unless we are able to complete the clinical trials required to support future submissions to the FDA, and unless the data generated by such trials supports the use of our system for the treatment of AF as safe and effective, we may not be able to secure additional FDA clearances or approvals and our ability to maintain and grow our business could be harmed.**

In order to obtain FDA approvals to promote the AtriCure bipolar ablation system for AF treatment, we will need to demonstrate in clinical trials that our system is safe and effective for such use. In order to conduct clinical trials, it is necessary to receive an investigational device exemption, or IDE, from the FDA. While we have obtained the required IDE from the FDA for the conduct of clinical trials for the use of our system as a treatment for AF during open-heart surgical procedures, the FDA or institutional review boards, or IRBs, that also oversee the trials for the purpose of protecting the study subjects can halt clinical trials at any time for safety reasons or because we or any of our clinical investigators do not follow the FDA's requirements for conducting clinical trials. In addition, the FDA may modify its requirements with respect to various aspects of our clinical study, in which case our ongoing clinical trial may not be achievable. Moreover, future clinical trials of our system to treat AF as a sole-therapy minimally invasive procedure will likely proceed in phases beginning with a feasibility trial. The FDA has granted us an IDE to conduct a feasibility study relating to the use of the AtriCure bipolar system for the sole-therapy minimally invasive treatment of AF, but there is no guarantee that the FDA will grant us approval to conduct broader clinical trials. If we are unable to receive approval to conduct broader clinical trials or the trials are halted by the FDA or others, we would not be able to promote the AtriCure bipolar ablation system for use in the treatment of AF in the United States.

While we have begun the RESTORE-SR trial, a clinical trial to support the submission of our PMA seeking FDA approval to use the AtriCure bipolar ablation system for the treatment of AF during elective open-heart procedures, enrollment in the trial has been slower than expected. As of February 28, 2006, we had enrolled approximately 23.9% of the treatment patients and approximately 12.8% of the total patients required for this multicenter, 226-patient clinical trial. We cannot assure you that this clinical trial will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA.

We have begun the RESTORE-SR II study, a clinical study to evaluate the feasibility of using our system as a sole-therapy minimally invasive treatment for AF. This feasibility study is expected to enroll 25 patients at 5 leading US centers. A total of 17 patients have been treated in the study as of March 2, 2006 and we anticipate that enrollment and treatment of all 25 patients will be completed during the second quarter of 2006. We cannot assure you that this study or this trial will be completed in a timely manner or successfully or that the results obtained will be acceptable to the FDA.

Clinical trials and regulatory approval of the AtriCure bipolar ablation system for treatment of AF can take a number of years to accomplish and require the expenditure of substantial financial, managerial and other resources, and we may never obtain regulatory approval for the use of the AtriCure bipolar ablation system in either an open-heart procedure or a sole-therapy minimally invasive procedure. The FDA may not grant approval to use our system for the treatment of AF in all types of patients that experience AF, if any, or could limit the

type of AF that could be treated using our system. If we do not secure required FDA approval to promote the AtriCure bipolar ablation system for either or both types of procedures, our business, results of operations and prospects would be negatively affected as a result.

Further, we cannot make comparative claims regarding the use of the AtriCure bipolar ablation system against any alternative treatments without conducting comparative clinical studies, which would be expensive and time consuming. We do not have any current plans to conduct such comparative clinical studies to evaluate the AtriCure bipolar ablation system against any alternative method of treatment.

If the available data on the use of our system from clinical trials and marketing experience do not establish the safety or effectiveness of our system, our clinical trials may be halted, our system may be withdrawn from the market and we may be prohibited from further distribution and sale of our system.

If the results obtained from our clinical trials, any other clinical studies, or clinical or commercial experience indicate that our system is not safe or effective, or not as safe or effective as other treatment options, the FDA may not approve our system for the treatment of AF, adoption of the use of our system for the treatment of AF may suffer and our business would be harmed.

**We have experienced and may continue to experience unfavorable publicity relating to our business and our industry. This publicity has had and may continue to have a negative impact on our ability to attract and retain customers, our sales, clinical studies involving our products, our reputation and our stock price.**

We believe that we are experiencing a negative impact on our business from newspaper articles published in December 2005 and February 2006 relating to, among other things, concerns of conflicts of interest between the Cleveland Clinic and us, our compliance with FDA regulations for medical device reporting, and concerns that certain of our consultants who are involved with clinical studies of our products failed to adequately disclose their financial relationships with us.

In the wake of these articles, certain educational activities involving our products at the Cleveland Clinic and the University of Cincinnati were diminished. Although we understand that these educational activities are resuming at the Cleveland Clinic, we cannot assure you that these activities will reach their previous levels. In addition, Dr. Randall Wolf, one of our key consultants who has conducted clinical studies on the use of our system to treat AF and published articles relating to such studies, has reduced his involvement in educational activities at the University of Cincinnati and he is recovering from back surgery. In light of Dr. Wolf's diminished involvement with educational activities and this unfavorable publicity, we are uncertain as to whether the educational activities involving our products at the University of Cincinnati will resume their previous levels. We also understand that the University of Cincinnati has initiated an internal review to validate the data obtained from two clinical studies involving our system that were conducted by Dr. Wolf. We cannot assure you that this data will be validated and we cannot predict with certainty the effect that any failure to validate this data would have on us.

Because these articles relate to the validity of important clinical data on the use of our system and involve Dr. Wolf and two of the pioneering institutions which have been proponents and investigators of our system, some current and potential customers have been and may continue to be reluctant to purchase our system. We also believe that this publicity has had and may continue to have a negative impact on clinical studies involving our products. We cannot assure you that this publicity or similar unfavorable publicity will not adversely impact future clinical studies involving our products or adversely impact our current or future submissions to the FDA.

We believe that this publicity has had and may continue to have a negative impact on our business, results of operations, financial condition and stock price. We also believe that future unfavorable publicity could cause other adverse effects, including a further decline in the price of our stock.

**We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.**

Our business and future growth depend on the continued use of the AtriCure bipolar ablation system in the treatment of AF, which is considered an off-label use of our system because the sole indication for which our

system has received FDA clearance or approval is the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures. Under the Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products, including our system, for off-label uses. This means that we may not make claims about the safety or effectiveness of the AtriCure bipolar ablation system for the ablation of cardiac tissue or the treatment of AF and may not proactively discuss or provide information on the use of our system for the treatment of AF, except in certain limited scientific and other settings.

Due to these legal constraints, our sales and marketing efforts focus only on the general technical attributes and benefits of the AtriCure bipolar ablation system and not on the use of our system for AF treatment or other cardiac uses. At the same time, we provide certain support for the use of the AtriCure bipolar ablation system in the treatment of AF that we believe is non-promotional and therefore permitted. In particular, since our system is only being used by doctors for the treatment of AF, we train our sales force on the use of our system by cardiothoracic surgeons to treat AF, and off-label sales are included in our sales force compensation structure. Sales personnel call on cardiothoracic surgeons, electrophysiologists, and other doctors to discuss the general attributes of our system and respond in a non-promotional manner to unsolicited requests for information from doctors on the use of our system in the treatment of AF by providing copies of and citations to peer-reviewed journal articles and/or other training and instructional tools. In addition, medically trained clinical application specialists attend surgical procedures to discuss the general attributes of our system and respond to unsolicited requests for information on the use of our system for the treatment of AF. We have entered into consulting agreements with prominent cardiothoracic surgeons and electrophysiologists who assist us with, among other things, product development and clinical development. In addition, we provide financial support in the form of research and educational grants to several leading institutions in the cardiac field, which they may use to conduct physician training programs, including programs relating to the surgical treatment of AF using our system. We also provide some guidance to physicians and medical institutions regarding what physicians are available and qualified for training other physicians on the use of our system in the treatment of AF. We also continue to make improvements in our system which could be viewed as supporting the ablation of cardiac tissue and the treatment of AF.

There is a material risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of these activities constitute the promotion of our system for a non-FDA-approved use in violation of the law. We also face the risk that FDA or other regulatory authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. For example, in November 2004, we received a letter from the FDA relating to certain cardiac-related information on our website in connection with the AtriCure bipolar ablation system, which we subsequently removed. There is also a possibility that we could be enjoined from making sales of the AtriCure bipolar ablation system for any non-FDA-approved use, which effectively would bar all sales of our system until we receive FDA clearances or approval, if ever. In addition, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

**The use of products we sell may result in injuries or other adverse events that lead to product liability suits, which could be costly to our business or our customers' business.**

The use of products we sell may result in a variety of serious complications, including damage to the heart, internal bleeding, death, or other adverse events, potentially leading to product liability claims. Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our system was

used. Although our manufacturing processes and those of our suppliers are required to comply with the FDA's quality system regulations, or QSR, covering the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products, if products we sell are defectively designed, manufactured or labeled, contain inadequate warnings, contain defective components or are misused, we may become subject to costly litigation by our customers or their patients.

We carry product liability insurance that is limited in scope and amount and may not be adequate to fully protect us against product liability claims. We could be required to pay damages that exceed our insurance coverage. Any product liability claim, with or without merit, could result in an increase in our product liability insurance rates or our inability to secure coverage on reasonable terms, if at all. Even in the absence of a claim, our insurance rates may rise in the future. Any product liability claim, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, withdrawal of clinical trial volunteers, injury to our reputation and loss of revenue. Any of these events could negatively affect our earnings and financial condition.

**Our current inability to educate or train doctors in the use of the AtriCure bipolar ablation system for the treatment of AF, due to legal prohibitions on off-label promotion of medical devices, could result in injuries to patients or other adverse events that lead to litigation against us, which could be costly to our business.**

Our sales team educates doctors in the technology and general application of the AtriCure bipolar ablation system, but we cannot currently educate or train doctors to use our system for the ablation of cardiac tissue or for the surgical treatment of AF. Hospitals and universities offer independent educational programs for the treatment of AF utilizing the AtriCure bipolar ablation system, and there is independent doctor-to-doctor training to use our system for the treatment of AF. We do not require that doctors who use the AtriCure bipolar ablation system have any specific training in the use of our system. We cannot assure you that doctors utilizing our system are using it correctly. Because we rely on training by hospitals and universities and doctor-to-doctor training, we do not control the quality of the training received by the doctors who use our system. Not requiring training on the use of our system may expose us to greater risk of product liability for injuries occurring during procedures utilizing the AtriCure bipolar ablation system. If demand for the AtriCure bipolar ablation system grows, the increased number of procedures performed using our system may potentially lead to more injuries and an increased risk of product liability. In addition, the off-label use of our system by the doctors may expose us to greater risks relating to product liability claims.

**Serious complications arising out of surgical procedures for the treatment of AF, including surgical AF treatments involving our system, could harm our business in a variety of important ways.**

Serious complications, including death, have been encountered in connection with the surgical treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our system was used. The rate of serious complications associated with surgical AF treatments in general, or surgical AF treatments involving the use of our system in particular, may be greater than the rate of serious complications associated with alternative therapies for the treatment of AF or AF itself.

Adverse outcomes, or the perception that surgical AF treatments, including treatments involving the use of our system, are not safe, could harm our business, including in the following ways:

- our system may fail to gain or may lose market acceptance;
- the market for the sole-therapy minimally invasive treatment of AF may fail to develop;
- the medical community may fail to adopt our system for the sole-therapy minimally invasive treatment of AF;
- the FDA or foreign regulatory authorities may revoke the clearances or approvals they have granted for the use of our system for the ablation of soft tissue;

- the FDA or foreign regulatory authorities may refuse, delay or revoke clearances, approvals or clinical trials of our system for the ablation of cardiac tissue or the treatment of AF; and
- the FDA or other domestic or foreign regulatory or enforcement authorities may be more likely than otherwise to pursue an action against us for promoting our products for off-label uses.

The significance of each of these identified risks is discussed elsewhere under the caption “Risks Relating To Our Business.”

**Competition from existing and new products and procedures may decrease our market share and cause our revenue to decline.**

The medical device industry, including the market for the treatment of AF, is highly competitive, subject to rapid technological change and significantly affected by new product introductions and promotional activities of other participants. We cannot assure you that the AtriCure bipolar ablation system will compete effectively against drugs, catheter-based ablation, implantable devices such as pacemakers or defibrillators, other bipolar ablation systems or other surgical AF treatments, which may be more well-established among doctors and hospitals. Many companies are promoting devices for the treatment of AF, and we anticipate that new or existing competitors may develop competing products, procedures or clinical solutions. There are few barriers to prevent new entrants or existing competitors from developing products to compete directly with ours. Some companies also compete with us to attract qualified scientific and technical personnel as well as funding. Our primary competitors include Guidant Corp., Medtronic, Inc., St. Jude Medical Inc., Boston Scientific Corporation, Edwards Lifesciences Corporation and CryoCath Technologies Inc. These companies are larger than us or enjoy competitive advantages, including:

- broader product offerings;
- established and more comprehensive distribution networks;
- less expensive products and procedures that take less time to perform;
- greater resources, including financial resources and more extensive experience in product development, manufacturing, regulatory clearance and approval, promotion, distribution and selling and patent litigation; and
- established relationships with hospitals, healthcare providers and payors.

Some competitors have FDA clearance for the use of their products to ablate cardiac tissue or FDA approval for the use of their products to ablate cardiac tissue during open-heart surgery. Our competitors are currently conducting clinical trials for the use of their products in the treatment of AF, which if successful, may impact the future sales of the AtriCure bipolar ablation system. Furthermore, demand for the AtriCure bipolar ablation system could be diminished by equivalent or superior products and technologies being offered by competitors, including products utilizing bipolar technology which could prove to be more effective, faster, safer or less costly than the AtriCure bipolar ablation system. The introduction of new products, procedures or clinical solutions by competitors may result in price reductions, reduced margins or loss of market share and may render our products obsolete, which could adversely affect our net revenue and future profitability.

**Our intellectual property rights may not provide meaningful commercial protection for our products, which could enable third parties to use our technology or methods, or very similar technology or methods, and could reduce our ability to compete.**

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us

to gain or keep any competitive advantage. Our patent applications may not issue as patents at all or in a form that will be advantageous to us. Our issued patents and those that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Although we have taken steps to protect our intellectual property and proprietary technology, we cannot assure you that third parties will not be able to design around our patents or, if they do infringe upon our technology, that we will be successful in or have sufficient resources to pursue a claim of infringement against those third parties. We believe that third parties may have developed or are developing products that could infringe upon our patent rights. Any pursuit of an infringement claim by us may involve substantial expense or diversion of management attention. In addition, although we have entered into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, investigators and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Foreign countries generally do not allow patents to cover methods for performing surgical procedures. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position.

**The medical device industry is characterized by patent litigation and any litigation or claim against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights.**

Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Any patent dispute, even a meritless or unsuccessful one, would be time consuming and expensive to defend and could result in the diversion of our management's attention from our business and result in adverse publicity, the disruption of development and marketing efforts, injury to our reputation and loss of revenue. Any of these events could negatively affect our earnings and financial condition.

Our competitors or others may assert that the AtriCure bipolar ablation system or the methods employed in the use of our system infringe on United States or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued and pending patents relating to surgical ablation, the surgical treatment of AF and other surgical devices. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our system may infringe. There could also be existing patents of which we are unaware that one or more components of our system may inadvertently infringe. As the number of competitors in the market for the treatment of AF grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

If a third-party's patents were upheld as valid and enforceable and we were found to be infringing, we could be prevented from selling the AtriCure bipolar ablation system unless we were able to obtain a license to use technology or ideas covered by such patent or are able to redesign our system to avoid infringement. A license may not be available at all or on terms acceptable to us, and we may not be able to redesign our products to avoid any infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. If we are not successful in obtaining a license or redesigning our products, we may be unable to sell our products and our business could suffer.

**We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at other medical device companies. Although there are no claims currently pending against us, we may be subject to future claims that these employees, or we, have

inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research or sales personnel or their work product could hamper or prevent our ability to improve our products or sell our existing products, which would harm our business.

**The increase in cost of medical malpractice premiums to doctors and hospitals or the lack of malpractice insurance coverage due to the use of our system by doctors for an off-label indication may cause certain doctors or hospitals to decide not to use our system and may damage our ability to grow and maintain the market for our system.**

Insurance carriers have been raising premiums charged for medical malpractice insurance due, at least in part, to increased risks associated with off-label procedures, including higher damage awards for successful plaintiffs. Insurance carriers may continue to raise premiums or they may deny malpractice coverage for procedures performed using products such as ours on an off-label basis. If this trend continues or worsens, our revenue may fall as doctors or hospitals decide against purchasing the AtriCure bipolar ablation system due to the cost or unavailability of insurance coverage.

**We have a limited history of operations and a history of net losses available to common shareholders and we may never become profitable.**

We have a limited operating history and have incurred net losses each year since our inception, including net losses available to common shareholders of approximately \$12.7 million in 2005, approximately \$9.5 million in 2004 and approximately \$7.1 million in 2003. As of December 31, 2005, we had an accumulated deficit of approximately \$42.3 million.

Our net losses available to common shareholders have resulted principally from costs and expenses relating to sales and promotional efforts, research and development, seeking regulatory clearances and approvals, and general operating expenses. We expect to continue to make substantial expenditures and to incur additional operating losses in the future as we expand our sales, manufacturing, marketing and product development activities, increase our administrative staff and further develop and commercialize our products, including completing clinical trials and seeking regulatory clearances and approvals for the AtriCure bipolar ablation system. If sales of our system do not continue to grow as we anticipate, we will not be able to achieve profitability. Our expansion efforts may prove more expensive than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and shareholders' deficit and we may never become profitable.

**Our federal tax net operating loss carryforwards will be limited or lost, resulting in greater income tax expense because we experienced an ownership change of more than 50 percentage points upon the initial public offering of our common stock.**

In connection with our initial public offering in August 2005, we experienced an ownership change as defined by the Internal Revenue Code of 1986 that will limit the availability of our net operating loss carryforwards to offset any future taxable income, which may increase our future income tax expense. Our inability to use these net operating loss carryforwards to reduce taxable income is based on an ownership change of more than 50 percentage points under rules contained in the United States Internal Revenue Code. We had federal income tax net operating loss carryforwards of approximately \$23.7 million at December 31, 2005 that, if not utilized to reduce our taxable income, will begin to expire in 2021.



**Our capital needs after the next 12 months are uncertain and we may need to raise additional funds in the future and such funds may not be available on acceptable terms, if at all.**

We believe that our current cash, cash equivalents and short-term investments, will be sufficient to meet our projected capital requirements for at least the next 12 months. Our capital requirements will depend on many factors, including:

- the revenue generated by sales of our products;
- the costs associated with expanding our manufacturing and marketing activities, as well as sales and distribution efforts;
- the rate of progress and cost of our research and development activities;
- the costs of obtaining and maintaining FDA and other regulatory clearances and approvals of, and intellectual property protection for, our products and products in development;
- the effects of competing technological and market developments; and
- the number and timing of acquisitions and other strategic transactions.

As a result of these factors, we may need to raise additional funds, and we cannot be certain that such funds will be available to us on acceptable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing shareholders may experience dilution, and if we issue equity or debt securities, such securities may have rights, preferences and privileges senior to those of our existing shareholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our future products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to expand our operations, develop new products, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

**If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected and our growth could be limited.**

The growth that we have experienced and that we may experience in the future requires us to rapidly expand our sales personnel and manufacturing operations. Our United States sales and training force increased from 10 employees on January 1, 2003 to 51 employees as of December 31, 2005. As a result of the closing of the initial public offering in August 2005, we purchased Enable, the manufacturer of our single-use disposable ablation clamps. As of December 31, 2005, we had a total of 160 employees. Rapid expansion in personnel could result in unanticipated costs and disruptions to our operations. Organizational growth could strain our existing managerial, operational, financial and other resources. We will need to expand our current, or implement new, financial and operating systems, which may be costly and time-consuming.

For us to maintain and expand our business successfully, we must manufacture commercial quantities of our system's components, as well as components for other existing and future products, in compliance with regulatory requirements, including the FDA's Quality System Regulation, or QSR, at an acceptable cost and on a timely basis. Our anticipated growth may strain our ability to manufacture an increasingly large variety and supply of our products. Manufacturing facilities often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we cannot scale and manage our business or our manufacturing operations appropriately, maintain control over expenses or otherwise adapt to future growth, our growth may be impaired and our future revenue and operating results will suffer.

**We depend upon single and limited source third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.**

We currently rely on single and limited source third-party vendors for the manufacture of many of the components used in the AtriCure bipolar ablation system. For example, we rely on one vendor to manufacture

our ablation sensing unit, or ASU, and we have not been able to identify any alternate supplier to manufacture our ASU if it becomes unable to do so. In addition, in some cases there are relatively few, or no, alternative sources of supply for certain other components that are critical to the AtriCure bipolar ablation system. We also distribute a cryotherapy, or extreme cold, ablation device that doctors have used to make specialized lesions in the heart for the treatment of AF in addition to the lesions made by the AtriCure bipolar ablation system, and our inability to offer this device to potential users of our system could negatively affect sales of our system.

Our reliance on these outside manufacturers and suppliers also subjects us to risks that could harm our business, including:

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components may require product redesign and new submissions to the FDA which could significantly delay production or, if the FDA refuses to approve the changes, completely eliminate our ability to manufacture or sell our system;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Identifying and qualifying additional or replacement suppliers for any of the components used in the AtriCure bipolar ablation system, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, and could therefore have a material adverse effect on our business, financial condition and results of operations.

**An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.**

To mitigate the risk of supply interruptions, we may determine to maintain excess inventory of the products or components supplied to us by third parties. Managing our inventory levels is important to our cash position and results of operations. As we expand, managing our inventory levels becomes more difficult. An excessive amount of inventory reduces our cash available for operations and may result in excess or obsolete materials. Inadequate inventory levels may make it difficult for us to meet customer product demand, resulting in decreased revenue. An inability to forecast future revenue or estimated life cycles of products may result in inventory-related charges that would negatively affect our gross margins and results of operations.

**If we or our third party vendors fail to comply with extensive FDA regulations relating to the manufacturing of our product or any component part, we may be subject to fines, injunctions and penalties, and our ability to commercially distribute and sell our products may be hurt.**

Our manufacturing facility and the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility are required to comply with the FDA's quality systems regulations, or QSR, which sets forth minimum standards for the procedures, execution and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our systems. The FDA may enforce its QSR, among other ways, through periodic unannounced inspections. If our manufacturing facility or the manufacturing facility of any of our third-party component manufacturers, critical suppliers or third-party sterilization facility, fails a QSR inspection, our and

their operations could be disrupted, and manufacturing interrupted. Failure to take adequate and timely corrective action in response to an adverse QSR inspection could force a shutdown of our manufacturing operations or a recall of our products. Adverse QSR inspections could delay FDA approval of our system and could have an adverse effect on our production, sales and profitability. We and any of our third party vendors may also encounter other problems during manufacturing including failure to follow specific protocols and procedures, equipment malfunction and environmental factors, any of which could delay or impede our ability to meet demand. The manufacture of our product also subjects us to risks that could harm our business, including problems relating to the sterilization of our products or facilities and errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products. Any interruption or delay in the manufacture of the product or any of its components could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products, and could therefore have a material adverse effect on our business, financial condition and results of operations.

**If we fail to comply with the extensive FDA regulations relating to our business, we may be subject to fines, injunctions and penalties and our ability to commercially distribute and promote our products may be hurt.**

Our products are classified by the FDA as medical devices and as such are subject to extensive regulation in the United States by the FDA and numerous other federal, state and foreign governmental authorities. FDA regulations, guidance, notices and other issuances specific to medical devices are broad and regulate, among other things:

- product design, development, manufacturing and labeling;
- product testing, including electrical testing, transportation testing and sterility testing;
- pre-clinical laboratory and animal testing;
- clinical trials in humans;
- product safety, effectiveness and quality;
- product manufacturing, storage and distribution;
- premarket clearance or approval;
- record keeping and document retention procedures;
- product advertising, sales and promotion;
- post-market surveillance and medical device reporting, including reporting of deaths, serious injuries or other adverse events or device malfunctions;
- product corrective actions, removals and recalls; and
- import and export.

Compliance with FDA, state and other regulations can be complex, expensive and time-consuming. The FDA and state authorities have broad enforcement powers. Furthermore, changes in the applicable governmental regulations could prevent further commercialization of our products and technologies and could materially harm our business.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

- refusing or delaying our pending requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, we could lose customers, and our production, product sales, business, results of operations and financial condition would be harmed.

We are also subject to medical device reporting regulations that require us to file reports with the FDA if our products reasonably are the cause of or contribute to an adverse event, death, serious injury or in the event of product malfunction. As of March 15, 2006, we have submitted a total of thirteen medical device reports to the FDA involving our products. There have also been other incidents, including patient deaths, that have occurred during open-heart and sole-therapy minimally invasive procedures using our system that we have not, and believe were not required to be, reported to the FDA because we determined that these incidents were not related to the use of our system. If the FDA disagrees with us, however, and determines that we should have submitted reports for these adverse events, we could be subject to significant regulatory fines or other penalties. In addition, the number of medical device reports we make, or the magnitude of the problems reported, could cause the FDA or us to terminate or modify our clinical trials or recall or cease the sale of our products, and could hurt commercial acceptance of our product in the market.

**Modifications to the AtriCure bipolar ablation system may require new clearances or approvals or require us to cease promoting or recall the modified products until such clearance or approvals are obtained.**

Any modification to a 510(k)-cleared device that would constitute a change in its intended use, design or manufacture, could require a new 510(k) clearance or, possibly, submission and FDA approval of a PMA. The FDA requires every medical device company to make the determination as to whether a new 510(k) is to be filed in the first instance, but the FDA may review any medical device company's decision. We have previously made modifications to the AtriCure bipolar ablation system but do not believe such modifications require us to submit an additional 510(k) clearance. The FDA may not agree with our decisions regarding whether new clearances or approvals are required. If the FDA disagrees with us and requires us to submit a new 510(k) or PMA for then-existing modifications, we may be required to cease promoting or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or other penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

**We will spend considerable time and money complying with federal, state and foreign regulations in addition to FDA regulations, and, if we are unable to fully comply with such regulations, we could face substantial penalties.**

We are subject to extensive regulation by the federal government and the states and foreign countries in which we conduct our business. The laws that affect our ability to operate our business in addition to the Federal Food, Drug, and Cosmetic Act and FDA regulations include, but are not limited to, the following:

- state food and drug laws, including laws regulating the manufacture, promotion and distribution of medical devices;
- state consumer protection, fraud and business practice laws;
- the federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;

- the federal False Claims Act, which prohibits submitting a false claim or causing of the submission of a false claim to the government;
- Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid;
- the federal doctor self-referral prohibition, commonly known as the Stark Law, which, in the absence of a statutory or regulatory exception, prohibits the referral of Medicare patients by a doctor to an entity for the provision of certain designated healthcare services including inpatient and outpatient hospital services, if the doctor or a member of the doctor's immediate family has a direct or indirect financial relationship, including an ownership interest in, or a compensation arrangement with, the entity and also prohibits that entity from submitting a bill to a federal payor for services rendered pursuant to a prohibited referral;
- state laws that prohibit the practice of medicine by non-doctors and by doctors not licensed in a particular state, and fee-splitting arrangements between doctors and non-doctors, as well as state law equivalents to the Anti-Kickback Statute and the Stark Law, which may not be limited to government-reimbursed items;
- Federal and State healthcare fraud and abuse laws or laws protecting the privacy of patient medical information, including the Health Insurance Portability and Accountability Act, or HIPAA;
- the Federal Trade Commission Act and similar laws regulating advertising and consumer protection; and
- similar and other regulations outside the United States.

Certain federal and state laws regarding Medicare, Medicaid and physician self-referrals are broad and we may be required to change one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex and even minor, inadvertent irregularities in submissions can potentially give rise to claims that a statute has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. For example, if we were found to be in violation of the federal False Claims Act, we would likely face significant fines and penalties and would likely be required to change substantially our sales, promotion, grant and educational activities. There is also a possibility that we could face an injunction that would prohibit in whole or in part our current business activities, and, as a result of enforcement actions against us or our senior officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we, our distributors or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid and other government programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully or clearly interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

**If doctors or hospitals were to receive inadequate levels of reimbursement for surgical AF treatments using the AtriCure bipolar ablation system from governmental or other third-party payors, it could affect the adoption or use of our system and may cause our revenue to decline.**

Widespread adoption or use of the AtriCure bipolar ablation system by the medical community is unlikely to occur if doctors and hospitals do not receive sufficient reimbursement from payors for surgical treatment of AF using our system. Currently, hospitals do not receive any additional reimbursement from the fee-for-service Medicare program, which is administered by the Centers for Medicare and Medicaid Services, or CMS, for the cost of AF treatment, or for the cost of our system, as part of an open-heart procedure. However, doctors performing AF treatment during an open-heart surgical procedure do receive separate reimbursement for performing these AF treatments. Sole-therapy minimally invasive AF treatment does qualify for reimbursement from the fee-for-service Medicare program allowing both doctors and hospitals to receive reimbursement for this type of AF treatment. In addition, the Medicare program has already adopted specific hospital inpatient treatment codes describing AF treatment by ablation in sole-therapy minimally invasive procedures such as that provided through the use of the AtriCure bipolar ablation system.

Many private payors look to CMS as a guideline in setting their reimbursement policies and amounts. If CMS or other agencies decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare guidelines and those payors may reimburse only a portion of the cost of AF treatment or not at all. Furthermore, for some governmental payors, such as the Medicaid program, reimbursement differs from state to state, and some state Medicaid programs may not reimburse for our procedure in an adequate amount, if at all.

We are unable to predict all changes to the coverage or reimbursement methodologies that will be employed by private or governmental third-party payors. We cannot be certain that under prospective payment systems and applicable fee schedules, such as those used by CMS and by many private healthcare payors, the cost of the procedures utilizing the AtriCure bipolar ablation system will be adequately reimbursed or that it will receive reimbursement consistent with historical levels. Any denial of private or governmental third-party payor coverage or inadequate reimbursement for procedures performed using the AtriCure bipolar ablation system could harm our business and reduce our revenue.

**Adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would harm our ability to promote and sell the AtriCure bipolar ablation system.**

Third-party payors are increasingly exerting pressure on medical device companies to reduce their prices. Even to the extent that the treatment of AF using the AtriCure bipolar ablation system is reimbursed by private payors and governmental payors, adverse changes in payors' policies toward coverage and reimbursement for surgical AF treatment would also harm our ability to promote and sell the AtriCure bipolar ablation system. Payors continue to review their policies and can, without notice, deny coverage for treatments that include the use of our product. Because each third-party payor individually approves coverage and reimbursement, obtaining these approvals may be time-consuming and costly. In addition, third-party payors may require us to provide scientific and clinical support for the use of the AtriCure bipolar ablation system. Alternatively, government or private payors may deem the treatment of AF utilizing the AtriCure bipolar ablation system experimental or not medically necessary and, as such, not provide coverage.

Adverse changes in coverage and reimbursement for surgical AF treatment could harm our business and reduce our revenue.

**We have limited long-term clinical data regarding the safety and efficacy of the AtriCure bipolar ablation system. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect the rate at which our system is adopted by the medical community.**

Our success depends upon our system's acceptance by the medical community as safe and effective in the treatment of AF. Serious complications, including death, have been encountered in connection with the surgical

treatment of AF, including in connection with a limited number of sole-therapy minimally invasive procedures in which our system was used. Important factors upon which the efficacy of our system will be measured include long-term data on the number of patients that continue to experience AF following treatment with our system and the number of patients that have serious complications resulting from AF treatment using our system. Our clinical trials may produce limited data regarding the efficacy of our system for the treatment of AF, or may identify unexpected safety issues. We cannot provide any assurance that the data collected during our clinical trials will be compelling to the medical community or to the FDA, because it may not be scientifically meaningful and may not demonstrate that the AtriCure bipolar ablation system is an attractive procedure when compared against data from alternative procedures and products. In addition, the long-term effects of the AtriCure bipolar ablation system procedure are not known.

The results of short-term clinical experience of the AtriCure bipolar ablation system do not necessarily predict long-term clinical benefit. If the long-term clinical trial results are not as positive as the short-term results or the long-term results do not otherwise meet doctors' expectations, the FDA may not approve our system for the treatment of AF, the AtriCure bipolar ablation system may not become widely adopted, and doctors may recommend alternative treatments for their patients. Another significant factor is acute safety data on complications that occur during the treatment of AF during open-heart surgical procedures and as a sole-therapy minimally invasive treatment.

If the results obtained from our RESTORE-SR trial or any other clinical studies or clinical or commercial experience indicate that the AtriCure bipolar ablation system is not safe or effective, or not as safe or effective as other treatment options or than current short-term data would suggest, the FDA may not approve our system for the treatment of AF, adoption of the use of our system for the treatment of AF may suffer and our business would be harmed.

Even if we believe the data collected from clinical studies or clinical experience indicates positive results, each doctor's actual experience with our system may vary. Clinical studies conducted with our system have involved procedures performed by doctors who are technically proficient. Consequently, both short- and long-term results reported in these studies may be significantly more favorable than typical results of practicing doctors, which could negatively impact rates of adoption of the AtriCure bipolar ablation system.

**We sell the AtriCure bipolar ablation system outside of the United States and are subject to various risks relating to international operations, which could harm our international revenue and profitability.**

During the twelve months ended December 31, 2005, approximately 8.7% of our total revenue was attributable to sales in markets outside of the United States. We currently depend on third-party distributors to sell the AtriCure bipolar ablation system outside of the United States, and if these distributors underperform, we may be unable to increase or maintain our level of international revenue. Over the long term, we intend to grow our business outside of the United States, and to do so we will need to attract additional distributors or hire direct sales personnel to expand the territories in which we sell the AtriCure bipolar ablation system. Distributors may not commit the necessary resources to promote and sell our system to the level of our expectations. If current or future distributors do not perform adequately, or we are unable to locate distributors in particular geographic areas, we may not realize expected long-term international revenue growth.

Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory laws and requirements in each jurisdiction where we operate or have sales. Our or our distributors' failure to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or they have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations. Moreover, if political or economic conditions deteriorate in these countries, our ability to conduct our international operations could be

limited and the costs could be increased, which could negatively affect our operating results. Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including:

- export restrictions and controls relating to technology;
- pricing pressure that we may experience internationally;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs and other trade barriers;
- the need to hire additional personnel to promote our system outside of the United States;
- international terrorism and anti-American sentiment;
- fluctuations in exchange rates for future sales denominated in non-United States currency; and
- difficulties in obtaining and enforcing intellectual property rights.

Our exposure to each of these risks may increase our costs and require significant management attention. We cannot assure you that one or more of these factors will not harm our business.

**If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained and maintained, sales of the AtriCure bipolar ablation system outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.**

Our revenue generated from sales outside of the United States is also dependent upon the availability of coverage and reimbursement within prevailing foreign healthcare payment systems. In general, foreign healthcare payors do not provide reimbursement for sole-therapy minimally invasive procedures utilizing an ablation device such as the AtriCure bipolar ablation system. In addition, healthcare cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we sell our system, and these efforts are expected to continue. To the extent that use of an ablation device such as the AtriCure bipolar ablation system has historically received reimbursement under a foreign healthcare payment system, if any, such reimbursement has typically been significantly less than the reimbursement provided in the United States. If coverage and adequate levels of reimbursement from governmental and third-party payors outside of the United States are not attained and maintained, sales of the AtriCure bipolar ablation system outside of the United States may decrease and we may fail to achieve or maintain significant sales outside of the United States.

**If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.**

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and technologies. Accordingly, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to successfully complete any acquisitions or joint ventures, or future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.



**We depend on our officers and other skilled and experienced personnel to operate our business effectively. If we are not able to retain our current employees or recruit additional qualified personnel, our business will suffer and our future revenue and profitability will be impaired.**

We are highly dependent on the skills and experience of our President and Chief Executive Officer, David J. Drachman, and other employees. We do not have any insurance in the event of the death or disability of our key personnel other than Mr. Drachman and Michael D. Hooven, our Chief Technology Officer. We do not currently have any employment agreements with any of our officers and they may terminate their employment and work elsewhere without notice and without cause or good reason. Currently we have non-compete agreements with our officers and other employees. Due to the specialized knowledge that each of our officers possesses with respect to the AtriCure bipolar ablation system and our operations and the limited pool of people with relevant experience in the medical device field, the loss of service of one or more of these individuals could significantly affect our ability to operate and manage our business. In particular, the departure of our Chief Technology Officer may impair our ability to develop new, advanced technologies. The announcement of the loss of one or more of our key personnel could negatively affect our stock price.

We depend on our scientific and technical personnel for successful product development and innovation, which are critical to the success of our business. In addition, to succeed in the implementation of our business strategy, our management team must rapidly execute our sales strategy, obtain expanded FDA clearances and approvals, achieve market acceptance for the AtriCure bipolar ablation system and further develop products, while managing anticipated growth by implementing effective planning, manufacturing and operating processes. Managing this growth will require us to attract and retain additional management and technical personnel. Our offices are located in West Chester, Ohio where it is difficult to attract and retain employees with experience in the medical device industry. We rely on direct sales employees and manufacturer's representatives to sell the AtriCure bipolar ablation system in the United States. We plan to expand our sales team and failure to adequately train our employees in the use and benefits of our products will prevent us from achieving our market share and revenue growth goals. In addition, we have key relationships with doctors that involve procedure and tool development, market development and clinical development. If any of these doctors end their relationship with us, our business would be negatively impacted. We cannot assure you that we will be able to attract and retain the personnel and doctor relationships necessary to grow and expand our business and operations. If we fail to identify, attract, retain and motivate these highly skilled personnel and doctors, we may be unable to continue our development and sales activities.

**Compliance with environmental laws and regulations may be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.**

Our manufacturing operations and research and development activities involve the use of biological materials and hazardous substances and are subject to a variety of federal, state and local environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances. Our research and development and manufacturing operations may produce biological waste materials, such as animal tissues, and certain chemical waste. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Compliance with these laws and regulations may be expensive and non-compliance could result in substantial liabilities. In addition, we cannot completely eliminate the risk of accidental contamination or injury to third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed any applicable insurance coverage we may have. In addition, our manufacturing operations may result in the release, discharge, emission or disposal of hazardous substances that could cause us to incur substantial liabilities, including costs for investigation and remediation.

## **Risks Relating To Our Common Stock**

**The price and trading volume of our common stock may experience extreme fluctuations and you could lose some or all of your investment.**

Because we operate within the medical device segment of the healthcare industry, our stock price is likely to be volatile. The market price of our common stock may fluctuate substantially due to a variety of factors, including:

- doctor and patient acceptance of the surgical treatment of AF using our system;
- adverse regulatory developments with respect to our products, such as recalls, new regulatory requirements, changes in regulatory requirements or guidance and timing of regulatory clearances and approvals for new products;
- coverage and reimbursement determinations for our products and the related procedures;
- the timing of orders received; delays or interruptions in manufacturing or shipping of our products;
- pricing of our products;
- media reports and publications and announcements about products or new innovations that could compete with our products or about the medical device product segment in general;
- market conditions or trends related to the medical device and healthcare industries or the market in general;
- additions to or departures of our key personnel;
- disputes, litigation or other developments relating to proprietary rights, including patents, and our ability to obtain patent protection for our technologies;
- changes in financial estimates, investors' perceptions or recommendations by securities analysts;
- variations in our quarterly financial and operating results; and
- changes in accounting principles.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. For example, we believe that recent negative publicity has caused and may continue to cause our stock price to decline.

If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market prices of the securities of medical device companies, particularly companies like ours without consistent product revenue and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. These market prices generally are not sustainable and are highly volatile. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our ability to grow our business.

**The future sale of our common stock could dilute your investment and negatively affect our stock price.**

We have approximately 12.1 million shares of common stock outstanding as of March 15, 2006. The 4,600,000 shares sold in our initial public offering are freely tradable without restriction under the federal securities laws unless purchased by our affiliates. The remaining shares of common stock outstanding are

available for public sale subject in some cases to volume and other limitations. Substantially all of these remaining shares were subject to lock-up agreements with certain underwriters that expired on February 1, 2006.

If our common shareholders sell substantial amounts of our common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could fall. The holders of up to approximately 6,000,000 shares of our common stock and the holders of warrants to purchase up to approximately 250,000 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

In addition, we may need to raise capital in the future to fund our operations. If we raise funds by issuing equity securities, our stock price may decline and our existing shareholders may experience significant dilution. Furthermore, we may enter into financing transactions at prices that represent a substantial discount to market price. A negative reaction by investors and securities analysts to any sale of our equity securities could result in a decline in the trading price of our common stock.

**If our principal shareholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions that may be favorable to you.**

As of December 31, 2005, our executive officers, directors and principal shareholders, and entities affiliated with them, beneficially owned in the aggregate greater than 50% of our common stock following our offering. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling shareholders. These shareholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our shareholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

**Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws and under Delaware law could inhibit a change in control or a change in management that you consider favorable.**

Provisions in our certificate of incorporation and bylaws could delay or prevent a change of control or change in management that would provide you with a premium to the market price of your common stock. These provisions include those:

- authorizing the issuance without further approval of “blank check” preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of shareholders to elect director candidates;
- limiting the ability to remove directors;
- limiting the ability of shareholders to call special meetings of shareholders;
- prohibiting shareholder action by written consent, thereby requiring all shareholder actions to be taken at a meeting of shareholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by shareholders at shareholder meetings.

In addition, Section 203 of the Delaware General Corporation Law limits business combination transactions with 15% shareholders that have not been approved by our board of directors. These provisions and others could make it difficult for a third party to acquire us, or for members of our board of directors to be replaced, even if doing so would be beneficial to our shareholders. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace the current management team. If a change of control or change in management is delayed or prevented, you may lose an opportunity to realize a premium on your shares of common stock or the market price of our common stock could decline.

**We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment.**

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Furthermore, pursuant to our credit facility with Lighthouse Capital Partners V, L.P., we are currently subject to restrictions on our ability to pay dividends and we may in the future become subject to other contractual restrictions on, or prohibitions against, the payment of dividends.

**The requirements of being a public company may strain our resources and distract management.**

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These requirements may place a strain on our systems and resources. The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. This may divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

We maintain our headquarters in West Chester, Ohio in a facility of approximately 12,200 square feet, which contains both office and warehouse space. We currently pay monthly rent of approximately \$10,000 and the lease for this facility expires in May 2009. In addition, we have three separate leases for a total of approximately 23,300 square feet of office, production and warehouse space in West Chester, Ohio, with an aggregate monthly rent of approximately \$15,000 and each lease for these facilities expires in 2010. We believe that our existing facilities are adequate to meet our immediate needs and that suitable additional space will be available in the future on commercially reasonable terms as needed.

**ITEM 3. LEGAL PROCEEDINGS**

We are not party to any material pending or threatened litigation, except as described below:

*Settlement with a competitor*

A competitor filed a suit against us in August 2005 that sought an injunction to prevent us from continuing to employ its former employee (who commenced employment with us two days earlier) as a sales representative

and that made related claims against the employee and us, including requests for damages in an unspecified amount. We and the other parties involved in this suit entered into a settlement agreement and mutual release effective November 18, 2005, which settlement did not have a material adverse effect upon us.

#### *Life Support Technology LST B.V.*

In January 2006 Life Support Technology LST B.V., a former distributor of our products in Europe, filed an action against us in Den Bosch, Netherlands and in February, 2006 LST also filed an action against our subsidiary, AtriCure Europe, B.V. in The Hague, Netherlands in the Kort Geding (a summary injunction proceeding wherein preliminary relief is demanded). On March 28, 2006, the case against our subsidiary was summarily dismissed. LST has until April 25, 2006 to file for an appeal of this decision.

We and LST were party to a distribution agreement, dated January 1, 2004. Each of LST's summonses allege that we, on behalf of AtriCure Europe, and LST reached an agreement, which would succeed a January 1, 2004 agreement, pursuant to which LST agreed to continue distributing our products in certain European countries. The summonses allege that, in addition to the value for LST of a continued distributorship, such agreement would have provided an additional \$330,000 to LST and its principal, J.L.M. Marinus. We believe that neither we nor our subsidiary reached such an agreement with LST and that the original distribution agreement with LST was terminated as of December 31, 2005. We intend to defend these lawsuits vigorously.

Pursuant to our January 1, 2004 distribution agreement with LST, certain of LST's obligations survive termination of that agreement. Such obligations include, among other things, the timely payment for equipment purchased and the return of all materials (such as marketing literature and sales and promotional materials) supplied by us to LST. In March 2006 we filed a complaint in Ohio State Court (Butler County, Ohio Court of Common Pleas) against LST claiming that LST has not complied with these obligations and we are seeking damages which, due to Ohio pleading limitations, are alleged to be more than \$25,000 but which, in fact, we believe are in an amount in excess of \$185,000.

We may from time to time become a party to additional legal proceedings.

#### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

#### **Executive Officers of the Registrant**

Set forth below is the name, age, position and a brief account of the business experience of each of our executive officers as of March 15, 2006.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
David J. Drachman .....	47	<i>President, Chief Executive Officer and Director</i>
Michael D. Hooven .....	50	<i>Chief Technology Officer and Director</i>
Thomas Etergino .....	39	<i>Vice President and Chief Financial Officer</i>
Stephen S. Cambridge .....	52	<i>Vice President, Sales</i>
Frederick Preiss .....	55	<i>Vice President, Operations</i>
Salvatore Privitera .....	39	<i>Vice President, Product Development</i>
Elsa Chi Abruzzo .....	38	<i>Vice President, Regulatory and Clinical Affairs</i>
James L. Lucky .....	44	<i>Vice President, Quality Assurance and Healthcare Compliance</i>

*David J. Drachman* has served as President, Chief Executive Officer and a director since October 2002. From 2000 to 2002, Mr. Drachman served as President of Impulse Dynamics N.V., a development stage medical device company focusing on implantable electrical solutions for the treatment of heart failure, diabetes and eating

disorders. From 1997 to 1999, Mr. Drachman served in a variety of positions, including Vice President of Strategic Development at Biosense Webster, Inc., a Johnson & Johnson, Inc. subsidiary that designs and manufactures diagnostic and therapeutic cardiac catheters. In addition, Mr. Drachman has also served in a variety of positions at Ventritex, Inc. and Boston Scientific Corporation. Mr. Drachman received his B.A. from the University of Louisville and holds North American Society of Pacing and Electrophysiology certification in Electrophysiology, Cardiac Pacing and Defibrillation.

*Michael D. Hooven* is one of our founders and has served as Chief Technology Officer and a director since August 2002 and as Chairman of the Board from August 2002 through February 2005. From November 2000 to August 2002, he served as our President and Chief Executive Officer. Since 1994, Mr. Hooven has served as Chairman of the Board, and has previously served as President and Chief Executive Officer of Enable, a developer and manufacturer of surgical instruments that Mr. Hooven co-founded and that we acquired on August 10, 2005. Mr. Hooven is also a director of Omeris, Inc., a not-for-profit company devoted to building and accelerating the bioscience industry, research and education and is a member of the advisory board of EnteraTech, Inc., a privately-held life sciences company. From 1986 to 1994, Mr. Hooven served as Director of New Product Development at Ethicon Endo-Surgery, Inc., a developer and manufacturer of minimally invasive surgical instruments. In addition, Mr. Hooven has also served in a variety of positions at Cordis Corporation and Siemens Medical Solutions of Siemens AG. Mr. Hooven received his B.S. and M.S. from the University of Michigan.

*Thomas Etergino*, CPA has served as our Vice President and Chief Financial Officer since May 2005. From 2003 to 2005, Mr. Etergino served as Chief Financial Officer of LSSi, Corp., a database developer. From 1998 to 2003, Mr. Etergino served in a variety of positions within DoubleClick Inc., including Chief Accounting Officer, Treasurer and Senior Vice President of Finance. Prior thereto, Mr. Etergino worked in Corporate Finance for Time Warner and spent eight years as an auditor at Coopers & Lybrand (now PricewaterhouseCoopers). Mr. Etergino received his B.S. from Washington & Lee University.

*Stephen S. Cambridge* has served as our Vice President, Sales since October 2005. From 2002 to 2004, Mr. Cambridge served as our Director of Sales and from January 2005 to October 2005, he led our Strategic Business Unit. Mr. Cambridge joined us in 2001 as our first sales person. From 1998 to 2001, Mr. Cambridge served as Vice President of Sales and Marketing for HealthBuyer.com, a medical finance company, which he co-founded. Mr. Cambridge has over 23 years of experience in sales and sales management, serving in a variety of positions for Cordis, Devices for Vascular Intervention, Inc., Cook, Inc. and AVE, Inc. Mr. Cambridge received his B.A. in Biological Science and his Master of Science in Science Education from Indiana University.

*Frederick Preiss* has served as our Vice President, Operations since May 2005. From 2002 to 2005, Mr. Preiss served as Vice President of Operations, OEM of Teleflex Medical, a medical device manufacturer and subsidiary of Teleflex, Inc., a publicly-held designer and manufacturer of specialty engineered devices for various industries. From 1998 to 2002, Mr. Preiss served as Vice President of Operations of Regeneration Technologies, a tissue-based biotechnology company. Prior thereto, from 1971 to 1998, Mr. Preiss held a number of responsible positions relating to operations, manufacturing, engineering and purchasing at various companies, including Wright Medical Technology, United States Surgical Corporation and Cyromedics Inc. Mr. Preiss received his B.S. from the University of New Haven.

*Salvatore Privitera* has served as our Vice President, Product Development since October 2003, and previously served in the same capacity from 2000 to 2001. From 2001 to 2003, Mr. Privitera served as Director of Product Development for Ethicon Endo-Surgery, a developer and manufacturer of minimally invasive surgical instruments. Mr. Privitera has 15 years of medical product development experience and has been associated with the release of over 30 medical devices in the fields of cardiac surgery, laparoscopic general surgery, breast biopsy, and sedation. He is a named inventor on over 20 issued and filed U.S. patents. Mr. Privitera received his B.S. from the University of Buffalo and his M.B.A. from Xavier University.

*Elsa Chi Abruzzo* has served as our Vice President, Regulatory and Clinical Affairs since February 2004. From 2002 to 2004, Ms. Abruzzo served as Senior Director, Regulatory and Clinical Affairs of Percutaneous Valve Technologies, Inc., a medical device manufacturer. From 1997 to 2002, Ms. Abruzzo served as Director of Regulatory Affairs and Manager of Regulatory Affairs of CryoLife, Inc., a publicly-held developer of implantable medical devices. Prior thereto, Ms. Abruzzo held a number of increasingly responsible positions in manufacturing, engineering, quality assurance, clinical research and regulatory affairs at various medical device companies, including Baxter International, Inc., Cordis Corporation and Cordis Endovascular (a subsidiary of Johnson & Johnson). Ms. Abruzzo received her B.S. from the University of Miami and is a Regulatory Affairs Certified Professional.

*James L. Lucky* has served as our Vice President, Quality Assurance and Healthcare Compliance since January 2004. From 1997 to 2004, Mr. Lucky served as Vice President of Quality Assurance and Regulatory Affairs for the medical segment of Teleflex, Inc., a publicly-held designer and manufacturer of specialty engineered devices for various industries. Prior to that position, Mr. Lucky held a number of quality assurance positions in the medical device industry, including at Ethicon Endo-Surgery, Inc., Bristol-Myers Squibb Company and Parker Hannifin Corp. Mr. Lucky received his B.S. from Western Michigan University, his M.S. from North Carolina State University and his M.B.A. from Duke University.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Common Stock Market Price

We closed our initial public offering on August 10, 2005. Our common stock is traded on the Nasdaq National Market under the symbol "ATRC". The following table sets forth the high and low closing sales price of our common stock since the date of our initial public offering through December 31, 2005.

	Price Range	
	High	Low
Fiscal Year 2005:		
Third Quarter (from August 10, 2005) .....	\$15.45	\$12.03
Fourth Quarter .....	\$14.32	\$10.50

As of March 15, 2006, the closing price of our common stock on the Nasdaq National Market was \$7.59 per share, and the number of stockholders of record was approximately 100.

#### Dividend Policy

Since our incorporation, we have never declared or paid any dividends on our capital stock. Furthermore, pursuant to our credit facility with Lighthouse Capital Partners V, L.P., we are currently subject to restrictions on our ability to pay dividends. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

#### Use of Proceeds from the Sale of Registered Securities

We registered the initial public offering of our common stock, par value \$.001 per share, on a Registration Statement on Form S-1, as amended (Registration No. 333-124197), which was declared effective on August 4, 2005. On August 10, 2005, we consummated an initial public offering of 4.6 million shares of our common stock at \$12.00 per share, which includes the underwriters' exercise of their over-allotment option, on August 9, 2005, to purchase 600,000 shares of our common stock, of which 450,000 shares were sold by selling shareholders and 150,000 shares were sold by us. Gross proceeds from the offering were \$49.8 million. We did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling shareholders. Total expenses from the offering were approximately \$6.6 million, which included underwriting discounts and commissions of approximately \$3.5 million and approximately \$3.1 million in other offering-related expenses. Proceeds to us from the offering after deducting underwriting discounts, commissions and offering expenses, were approximately \$43.2 million.

Of the \$43.2 million in net proceeds, through December 31, 2005, we have spent approximately \$6.4 million of the proceeds from the offering toward the acquisition of Enable Medical Corporation, approximately \$419,000 toward our obligations under a development and license agreement, and approximately \$3.3 million on other research and development activities and selling, general and administrative expenditures. Pending use of the remaining net proceeds of the offering, we intend to invest such proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments. The use of proceeds does not represent a material change from the use of proceeds described in the prospectus relating to the Registration Statement.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of our equity securities or to any other affiliates except for payments made to Epstein, Becker & Green P.C., our corporate counsel, for legal fees and expenses incurred in connection



with the offering. Theodore L. Polin, our corporate Secretary, is a shareholder of Epstein, Becker & Green P.C. Other than the exception described above, all offering expenses were paid directly to third parties who were not our directors or officers (or their associates), persons owning ten percent or more of our equity securities or any other affiliate.

### Recent Sales of Unregistered Securities

From January 1, 2005 to December 31, 2005, we granted options to purchase an aggregate of 688,082 shares of our common stock at an exercise price ranging from \$1.52 to \$13.89 per share.

In connection with the establishment of a credit facility with Lighthouse Capital Partners V, L.P. on March 8, 2005, we granted Lighthouse a warrant to purchase 55,208 shares of our common stock, or shares into which such series of stock is converted, at a price of \$11.29 per share. The warrant is exercisable at any time until August 10, 2006.

The grants of the options and warrants were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, or Regulation D and the other rules and regulations promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions not involving a public offering or transactions under compensatory benefit plans. The recipients of such options were our employees, directors or bona fide consultants and received the securities pursuant to our 2001 Stock Option Plan or 2005 Equity Incentive Plan. Each of the recipients of securities in these transactions had adequate access, through employment, business or other business relationships, to information about us.

### Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2005.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders .....	1,666,103	\$6.27	1,311,556
Equity compensation plans not approved by security holders .....	0	0	0
Total .....	<u>1,666,103</u>	<u>\$6.27</u>	<u>1,311,556</u>

Equity compensation plans approved by our stockholders include our 2001 Stock Option Plan and our 2005 Equity Incentive Plan.

## ITEM 6. SELECTED FINANCIAL DATA

The following tables reflect selected financial data derived from our consolidated financial statements for each of the last five years. The statement of operations data for the years ended December 31, 2005, 2004 and 2003, and the balance sheet data as of December 31, 2005 and 2004 are derived from our audited financial statements included in this Form 10-K and include the former operations of Enable Medical Corporation since its acquisition on August 10, 2005. The statement of operations data for the years ended December 31, 2002 and 2001, and the balance sheet data as of December 31, 2003, 2002 and 2001 are derived from our audited financial statements not included in this Form 10-K. Historical results are not necessarily indicative of future results. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K.

	Year ended December 31,				
	2005	2004	2003	2002	2001
(dollars in thousands, except share and per share data)					
<b>Operating Results:</b>					
Revenue .....	\$ 30,957	\$ 19,157	\$ 9,792	\$ 1,766	\$ 20
Cost of revenue .....	8,057	5,202	2,612	681	8
Gross margin percentage .....	74.0%	72.8%	73.3%	61.4%	60.0%
Operating expenses .....	33,703	19,591	10,537	6,747	3,152
Preferred stock interest expense .....	2,332	3,905	3,905	2,563	469
Net loss available to common shareholders .....	(12,683)	(9,452)	(7,108)	(9,031)	(3,596)
Basic and diluted net loss per share .....	\$ (2.10)	\$ (5.17)	\$ (3.97)	\$ (5.08)	\$ (2.04)
Weighted average shares outstanding .....	6,025,300	1,828,452	1,791,577	1,777,277	1,765,631
<b>Financial Position:</b>					
Cash, cash equivalents and short-term investments .....	\$ 33,802	\$ 5,175	\$ 10,399	\$ 15,434	\$ 1,890
Working capital .....	35,875	6,590	11,985	15,836	1,606
Total assets .....	50,040	12,731	14,759	17,586	2,051
Long-term obligations .....	1,084	—	—	—	—
Redeemable preferred stock .....	—	36,756	32,805	2	1
Accumulated deficit .....	(42,337)	(29,633)	(20,135)	(9,047)	(3,474)
Shareholders' equity (deficit) .....	43,183	(27,331)	(18,937)	17,020	1,731

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying financial statements and notes thereto contained in Item 8. Financial Statements and Supplementary Data, to provide an understanding of our results of operations, financial condition, and cash flows. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those set forth under "Risk Factors" and elsewhere in this Form 10-K.

### **Overview**

We develop, manufacture and sell innovative surgical devices designed to create precise lesions, or scars, in cardiac and soft tissues. Our primary product line is the AtriCure bipolar ablation system, which accounted for 94% of our revenue for the fiscal year ended December 31, 2005, 99% of our revenue for the fiscal year ended December 31, 2004 and 100% of our revenue for the fiscal year ended December 31, 2003. The AtriCure bipolar ablation system consists of a compact power generator known as an ablation sensing unit, or ASU, and several uniquely designed disposable ablation clamps that connect to the ASU, including two newly developed Isolator endoscopic ablation clamps that are specifically designed for use in sole-therapy minimally invasive procedures. We also market the Isolator bipolar pen and the Wolf dissector, which are separate from, but complement, our system. Medical journals have described the adoption by leading cardiothoracic surgeons of the AtriCure bipolar ablation system as a standard treatment alternative during open-heart surgical procedures to safely, rapidly and reliably create lesions in cardiac tissue to block the abnormal electrical impulses that cause atrial fibrillation, or AF, a rapid, irregular quivering of the upper chambers of the heart.

Cardiothoracic surgeons have used the AtriCure bipolar ablation system to treat AF in over 25,000 patients since its general commercial release in the United States in January 2003. We believe that our system is currently a market leader in the surgical treatment of AF during open-heart surgical procedures and surgeons have used our system as a sole-therapy minimally invasive treatment for AF, which is performed on patients who are not undergoing a separate open-heart procedure, on over 800 patients. We anticipate that substantially all of our sales for the foreseeable future will relate to the AtriCure bipolar ablation system for the treatment of AF.

From our inception in November 2000 through the first half of 2002, our operations consisted primarily of development-stage activities, including the development of the AtriCure bipolar ablation system, raising capital, obtaining product clearances, conducting product testing and evaluations, and recruiting personnel. After limited sales of our system in 2002, we commenced the general commercial release of our system in January 2003, generating total revenue of approximately \$9.8 million for 2003, \$19.2 million for 2004 and approximately \$31.0 million for 2005. We had a net loss available to common shareholders (after accrual of interest on our redeemable preferred stock) of approximately \$7.1 million for 2003, approximately \$9.5 million for 2004 and approximately \$12.7 million for 2005.

We currently sell the AtriCure bipolar ablation system to customers in the United States primarily through our direct sales force. We also sell our system outside of the United States, primarily in Asia, Europe, South America, Canada and the Middle East, through distributors who pay us in U.S. dollars. To date, our sales outside of the United States have been limited, constituting approximately 8.7% of our total revenue for 2005, approximately 7.4% of our total revenue for 2004 and approximately 3.2% of our total revenue for 2003. We expect international sales to be relatively constant as a percentage of sales for the foreseeable future. We have expanded our sales and training force in the United States from 26 employees as of December 31, 2004 to 51 employees as of December 31, 2005. We believe at this time our sales organization is appropriately sized and do not anticipate significant increases in the foreseeable future.

Our future growth will depend on our ability to generate sales of the AtriCure bipolar ablation system through increasing acceptance by the medical community of our system as a standard treatment alternative for

the surgical treatment of AF. Acceptance of our bipolar ablation system is dependent upon, among other factors, awareness and education of the medical community about the surgical treatment of AF, in general, and the safety and effectiveness of the AtriCure bipolar ablation system, in particular.

In 2001, the FDA cleared the AtriCure bipolar ablation system for the ablation and coagulation of soft tissues during certain non-cardiac-related surgical procedures, but our system has not been cleared or approved in the United States for the ablation of cardiac tissue or for the treatment of AF. In addition, in July 2005 we received FDA clearance for our single-use disposable Isolator bipolar pen for cardiac tissue ablation. As such, we may promote this device to doctors and provide education and training on the use of our pen device for that use. We do not believe that our AtriCure bipolar ablation system is currently being used for its FDA-cleared indications and, accordingly, substantially all of our revenue is currently generated through the non-FDA-approved, or off-label, use of our system for the treatment of AF. While the FDA does not prevent doctors from using a product on an off-label basis, we cannot legally market a product for an off-label use. Because the AtriCure bipolar ablation system is currently our only significant product, the sustainability of our current operations, as well as our future viability, is dependent upon the continuation of sales of our system. We believe that sole-therapy minimally invasive treatment for AF represents the largest growth opportunity for us. If this market fails to develop, or the AtriCure bipolar ablation system is not widely adopted for use in this market, we may not achieve greater revenue or become profitable. In order to establish the sole-therapy minimally invasive AF treatment market, the current referral practices of physicians must change.

In June 2005, the FDA denied 510(k) clearance (approval to market a medical device in the United States based on a device being substantially equivalent to an already cleared device) for use of our bipolar ablation system to ablate cardiac tissue because the FDA determined that our system is not substantially equivalent to an already cleared device. The FDA has taken a position that all radio-frequency surgical clamps are not general cardiac tools because they are specifically designed and intended for use in surgical ablation to treat AF. As such, no radio-frequency surgical clamps from any medical device company, including ours, have been cleared for cardiac ablation to date. This means that we would now be required to gain FDA approval to market the device through the submission of a pre-market approval application, or PMA, a lengthier process, in order to gain FDA approval of our system for the cardiac indication. While we may appeal the FDA's decision, that clearance would not eliminate the need to seek FDA approval through a separate PMA for the use of our system to treat AF. After conducting necessary clinical trials, we intend to seek FDA approval as early as 2009 for the use of our system to treat AF, which we view as our market opportunity. If lack of FDA clearance or approval of our system for the treatment of AF were to prevent sales of our system, not only would we no longer receive revenue from the sale of our system, but we also would require significant financing to conduct clinical trials and to sustain our operations until such time as sales could resume. We cannot assure you that we can obtain these FDA approvals, that we would have, or could raise, sufficient financial resources to sustain our operations pending FDA approval, or that, if and when the required approvals are obtained, there will be a market for the AtriCure bipolar ablation system.

Our costs and expenses consist of cost of revenue, research and development expenses and selling, general and administrative expenses. Cost of revenue consists principally of the cost of purchasing materials and manufacturing our products. Research and development expenses consist principally of expenses incurred with respect to internal and external research and development activities and the conduct of clinical trials. With the FDA's authorization, we have begun the RESTORE-SR clinical trial relating to the use of the AtriCure bipolar ablation system to treat AF during open-heart surgery. A total of 29 patients have been enrolled in the clinical trial as of February 28, 2006, approximately 12.8% of the patients required for this multicenter, 226-patient clinical trial. We have also obtained FDA approval to conduct the RESTORE-SR II clinical study to evaluate the feasibility of using our system as a sole-therapy minimally invasive treatment for AF. This feasibility study is expected to enroll 25 patients at 5 leading US centers. A total of 17 patients have been treated in the study as of March 2, 2006 and we anticipate that enrollment and treatment of all 25 patients will be completed during the second quarter of 2006. Selling, general and administrative expenses consist principally of costs associated with our sales and administrative functions, accounting and legal fees and educational grants to medical institutions.

We expect our operating expenses to continue to increase in the future in absolute dollar terms and as a percentage of revenue as a result of increased sales and marketing expenses incurred to foster our revenue growth, continued research and development, increased general and administrative expenses to keep pace with our overall growth, the costs of being a public company and costs associated with seeking FDA approval of our system for use in the surgical treatment of AF.

We believe that we are experiencing a negative impact on our business from newspaper articles published in December 2005 and February 2006 relating to, among other things, concerns of conflicts of interest between the Cleveland Clinic and us, our compliance with FDA regulations for medical device reporting, and concerns that certain of our consultants who are involved with clinical studies of our products failed to adequately disclose their financial relationships with us.

In the wake of these articles, certain educational activities involving our products at the Cleveland Clinic and the University of Cincinnati were diminished. Although we understand that these educational activities are resuming at the Cleveland Clinic, we cannot assure you that these activities will reach their previous levels. In addition, Dr. Randall Wolf, one of our key consultants who has conducted clinical studies on the use of our system to treat AF and published articles relating to such studies, has reduced his involvement in educational activities at the University of Cincinnati and he is recovering from back surgery. In light of Dr. Wolf's diminished involvement with educational activities and this unfavorable publicity, we are uncertain as to whether the educational activities involving our products at the University of Cincinnati will resume their previous levels. We also understand that the University of Cincinnati has initiated an internal review to validate the data obtained from two clinical studies involving our system that were conducted by Dr. Wolf. We cannot assure you that this data will be validated and we cannot predict with certainty the effect that any failure to validate this data would have on us.

Because these articles relate to the validity of important clinical data on the use of our system and involve Dr. Wolf and two of the pioneering institutions which have been proponents and investigators of our system, some current and potential customers have been and may continue to be reluctant to purchase our system. We also believe that this publicity has had and may continue to have a negative impact on clinical studies involving our products. We cannot assure you that this publicity or similar unfavorable publicity will not adversely impact future clinical studies involving our products or adversely impact our current or future submissions to the FDA.

We believe that this publicity has had and may continue to have a negative impact on our business, results of operations, financial condition and stock price. We also believe that future unfavorable publicity could cause other adverse effects, including a further decline in the price of our stock.

## **Recent Developments**

### ***Initial Public Offering***

On August 10, 2005, we consummated an initial public offering of 4.6 million shares of our common stock at \$12.00 per share, which included the underwriters' exercise of their over-allotment option, on August 9, 2005, to purchase 600,000 shares of our common stock of which 450,000 shares were sold by selling shareholders and 150,000 shares were sold by us. We did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling shareholders. These share amounts reflect a 1-for-3.8 reverse split of our capital stock that was effected on July 27, 2005. In connection with the offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock. Proceeds to us from the offering, after deducting underwriting discounts, commissions and offering expenses, were \$43.2 million. Offering expenses were approximately \$3.1 million.

### ***Acquisition of Enable Medical Corporation***

On August 10, 2005 we acquired Enable Medical Corporation, the manufacturer of our single-use disposable ablation clamps. The results of operations formerly conducted by Enable have been included in our Consolidated Statements of Operations since that date. As a result of the acquisition, we expect to gain better control over manufacturing and supply chain activities, as well as enhance our engineering capabilities and improve our margins.

We paid approximately \$6.4 million to acquire Enable, net of \$0.8 million cash acquired. The aggregate purchase price was \$7.0 million, of which \$0.5 million was paid in February 2005 and the remaining \$6.5 million was paid in August 2005. We also incurred legal and professional expenses associated with the acquisition of approximately \$0.2 million. The purchase price reflects the expected growth potential of Enable and its profitability. As a result of this, the purchase price was in excess of the fair market value of the assets acquired, and we recorded goodwill of approximately \$3.8 million.

## Results of Operations

### *Years Ended December 31, 2005 compared to December 31, 2004*

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands) and as percentages of total revenue:

	Year Ended December 31,			
	2005		2004	
	Amount	% of Revenue	Amount	% of Revenue
Revenues . . . . .	\$ 30,957	100%	\$19,157	100%
Cost of revenues . . . . .	8,057	26%	5,202	27%
Gross profit . . . . .	22,900	74%	13,955	73%
Expenses:				
Research and development expenses . . . . .	9,109	29%	4,422	23%
Selling, general and administrative expenses . . . . .	24,594	80%	15,169	79%
Total operating expenses . . . . .	33,703	109%	19,591	102%
Loss from operations . . . . .	(10,803)	-35%	(5,636)	-29%
Preferred stock interest expense . . . . .	(2,332)	-7%	(3,905)	-20%
Other interest income (expense), net . . . . .	414	1%	106	0%
Other income . . . . .	85	0%	—	0%
Loss before taxes . . . . .	(12,636)	-41%	(9,435)	-49%
Income tax expense . . . . .	(47)	0%	(17)	0%
Net loss available to common shareholders . . . . .	<u>\$(12,683)</u>	<u>-41%</u>	<u>\$ (9,452)</u>	<u>-49%</u>

**Revenue.** Total revenue increased approximately \$11.8 million or 61.6%, from approximately \$19.2 million in 2004 to approximately \$31.0 million in 2005. The increase was primarily attributable to an increase of approximately 65% in the number of units sold of our bipolar ablation clamps, and new product launches, such as the Isolator bipolar pen. The increase in units sold of our previously existing product lines contributed approximately \$10.7 million of the total increase in sales, while the addition of the new bipolar pen product and other revenue contributed approximately \$1.0 million to the increase in revenue. Though our domestic and international sales were both favorably impacted by increases in average selling prices, the increase in our sales mix of lower priced international sales as a percentage of total sales resulted in a modest worldwide increase in our average selling price year over year, contributing approximately \$0.1 million to the overall revenue increase.

**Cost of revenue.** Cost of revenue increased approximately \$2.9 million, from approximately \$5.2 million in 2004 to approximately \$8.1 million in 2005. This increase resulted primarily from increased sales of products, additional depreciation associated with generators and cryo-units that are loaned at no cost to hospitals, a \$193,000 increase in our obsolescence reserve, and a \$266,000 write-off related to production equipment for discontinued products. These increases in cost of revenue were partially offset by our lower average cost per unit as a result of our third quarter acquisition of Enable Medical Corporation, the manufacturer of our single-use disposable ablation clamps. As a percentage of revenue, cost of revenue decreased from 27% in 2004 to 26% in 2005 due to our lower average cost per unit as discussed above.

**Research and development expenses.** Research and development expenses increased approximately \$4.7 million, from approximately \$4.4 million in 2004 to approximately \$9.1 million in 2005. The increase was primarily attributable to the addition of 25 full-time research and development personnel, including 13 former Enable employees, the expansion of our research and development activities to increase our product offerings and the expansion of our clinical trial activities. Our product development activities included projects to extend and improve the AtriCure bipolar ablation system, develop our new Isolator endoscopic ablation clamps, create new enabling devices such as new dissection, guidance and ablation tools, and research for new technologies. As a percentage of total revenue, research and development expenses increased from 23% in 2004 to 29% in 2005 due to increased spending on new product initiatives, expanded clinical trials and the addition of personnel. Research and development costs are expected to increase in 2006 both in absolute dollars and as a percentage of revenue primarily as a result of costs associated with the continued expansion of product development initiatives and clinical trials.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased approximately \$9.4 million, from approximately \$15.2 million in 2004 to approximately \$24.6 million in 2005. The increase was primarily attributable to an increase in headcount-related charges of approximately \$6.7 million, an increase in educational grants to medical institutions of approximately \$1.0 million, and an increase in general corporate expenditures of approximately \$1.7 million. The increase in headcount-related charges is primarily attributable to the acquisition of Enable and the addition of sales personnel who call on doctors to discuss the general attributes of our system, and respond in a non-promotional manner to unsolicited requests for information from physicians on the use of our system in the treatment of AF. As a percentage of total revenue, selling, general and administrative expenses remained relatively constant at approximately 79% for 2004 and 2005. Selling, general and administrative costs are expected to increase in 2006 in absolute dollars and as a percentage of revenue primarily as a result of increased costs associated with sales and marketing efforts and the increase in costs associated with being a public company.

**Preferred stock interest expense.** Preferred stock interest expense decreased approximately \$1.6 million, from approximately \$3.9 million in 2004 to approximately \$2.3 million in 2005. The decrease was attributable to the conversion of all shares of preferred stock into common stock upon the closing of our initial public offering on August 10, 2005.

**Other interest income, net.** Other interest income, net increased approximately \$308,000, from approximately \$106,000 in 2004 to approximately \$414,000 in 2005, due to the increased cash and cash equivalents resulting from the proceeds of our August 2005 initial public offering. The increase was partially offset by the interest expense incurred as a result of our long-term debt.

**Other income.** Other income was approximately \$85,000 in 2005. Other income consists of research grants that were recognized as a result of the Enable acquisition.

**Years Ended December 31, 2004 compared to December 31, 2003**

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands) and as percentages of total revenue:

	Year Ended December 31,			
	2004		2003	
	Amount	% of Revenue	Amount	% of Revenue
Revenues .....	\$19,157	100%	\$ 9,792	100%
Cost of revenues .....	5,202	27%	2,612	27%
Gross profit .....	13,955	73%	7,180	73%
Expenses:				
Research and development expenses .....	4,422	23%	2,501	26%
Selling, general and administrative expenses .....	15,169	79%	8,036	82%
Total operating expenses .....	19,591	102%	10,537	108%
Loss from operations .....	(5,636)	-29%	(3,357)	-35%
Preferred stock interest expense .....	(3,905)	-20%	(3,905)	-40%
Other interest income (expense), net .....	106	0%	154	2%
Other income .....	—	0%	—	0%
Loss before taxes .....	(9,435)	-49%	(7,108)	-73%
Income tax expense .....	(17)	0%	—	0%
Net loss available to common shareholders .....	<u>\$ (9,452)</u>	<u>-49%</u>	<u>\$ (7,108)</u>	<u>-73%</u>

**Revenue.** Revenue increased approximately \$9.4 million, from approximately \$9.8 million in 2003 to approximately \$19.2 million in 2004. The increase was primarily attributable to an increase of approximately 46% in the volume of units of our previously existing product line sold domestically and internationally and the addition of new products. The increase in units sold of our previously existing product line contributed approximately \$4.8 million of the total increase in sales, while the addition of new products contributed approximately \$5.4 million to the increase in revenue. While our average domestic selling price marginally increased in 2004 over 2003, the increase in lower priced international sales as a percentage of total sales resulted in a marginal decline in our overall average selling price year over year. This marginal decline in our selling price partially offset the overall revenue increase by approximately \$0.8 million. We obtained numerous new accounts, as the AtriCure bipolar ablation system was reviewed in industry journals and doctors more widely adopted the use of our system. Included in total revenue is approximately \$211,000 of commissions for 2004 from sales of certain cryotherapy products.

**Cost of revenue.** Cost of revenue increased approximately \$2.6 million, from approximately \$2.6 million in 2003 to approximately \$5.2 million in 2004 reflecting the approximate 100% increase in total units sold in 2004 as compared to 2003. Cost stability in our existing system and similar margin pricing strategies on our new product lines resulted in an increase in cost of revenue compared to 2003 consistent with the growth in total revenue since, as a percentage of revenue, cost of revenue remained the same at 27% for 2003 and 2004.

**Research and development expenses.** Research and development expenses increased approximately \$1.9 million, from approximately \$2.5 million in 2003 to approximately \$4.4 million in 2004. The increase was primarily attributable to the hiring of an additional 9 engineers in 2004, the expansion of our research and development activities to increase our product offerings and the expansion of our clinical trials. Our product development activities include projects to extend and improve the existing system, develop a new device platform, create new enabling devices such as new dissection, guidance and ablation tools, and research new technologies. As a percentage of total revenue, research and development expenses decreased from 26% in 2003 to 23% in 2004, due to the more rapid growth of revenue.



**Selling, general and administrative expenses.** Selling, general and administrative expenses increased approximately \$7.2 million, from approximately \$8.0 million in 2003 to approximately \$15.2 million in 2004. The increase was primarily attributable to an increase in headcount-related charges of approximately \$4.2 million, an increase in facilities-related charges of approximately \$0.9 million, and an increase in non-cash charges of \$1.0 million associated with certain option grants. Headcount-related charges were primarily attributable to the rapid expansion of our sales force to meet our growing market. These additional sales personnel call on doctors to discuss the general attributes of our system, and respond in a non-promotional manner to unsolicited requests for information from doctors on the use of our system in the treatment of AF. As a percentage of total revenue, selling, general and administrative expenses decreased slightly from 82% in 2003 to 79% in 2004.

In 2004, we recorded a compensation charge of approximately \$327,000 for stock options issued to employees that, subsequent to their issuance, were determined to have been issued with exercise prices below market value. The market value of these options was determined by applying a multiplier to our projected revenue. This value was then reduced by approximately 20% to reflect the illiquidity of the options. Given the fact that we are in a rapid growth phase, but are still unprofitable, we determined that applying a multiplier, determined by comparison to other rapidly growing healthcare companies of generally similar size to us, was the most appropriate valuation method.

**Other interest income, net.** Other interest income, net decreased slightly from approximately \$154,000 in 2003 to approximately \$106,000 in 2004, primarily due to decreased cash and cash equivalents.

### **Liquidity and Capital Resources**

Prior to our initial public offering, we financed our operations primarily through private sales of preferred stock, with aggregate net proceeds of approximately \$21.3 million of cash, excluding the conversion of approximately \$4.7 million of promissory notes.

In August 2005, we completed an initial public offering in which we received net proceeds, after deducting underwriting discounts, commissions and expenses, of approximately \$43.2 million from our sale and issuance of an aggregate of 4,150,000 shares of common stock, including 150,000 shares sold by us as part of the underwriters' over-allotment option. Offering expenses were approximately \$3.1 million.

As of December 31, 2005, we had cash, cash equivalents and short-term investments of approximately \$33.8 million and short-term and long-term debt of approximately \$1.4 million, resulting in a net cash position of approximately \$32.4 million. We had working capital of approximately \$35.9 million and an accumulated deficit of approximately \$42.3 million as of December 31, 2005.

**Cash flows used in operating activities.** Net cash used in operations was approximately \$7.6 million in 2005 and \$3.8 million in both 2004 and 2003. Net cash used in operations in 2005 was primarily attributable to a net loss of \$12.7 million and increases in inventory and prepaid expenses of \$0.2 million and \$0.7 million, respectively, as we increased our revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of \$0.7 million, depreciation and amortization of \$1.6 million, preferred stock interest of \$2.3 million and increases in payables and accrued liabilities of \$0.6 million due to our increase in operating expenses. Net cash used in operations in 2004 was primarily attributable to a net loss of \$9.5 million and increases in accounts receivable and inventory balances of \$1.9 million and \$0.4 million, respectively, as we increased our revenue, partially offset by adjustments for non-cash charges related to stock-based compensation of \$1.0 million, depreciation of \$1.0 million, preferred stock interest of \$3.9 million and increases in payables and accrued liabilities of \$2.4 million due to our increase in operating expenses. Net cash used in operations in 2003 was primarily attributable to a net loss of \$7.1 million and increases in accounts receivable, inventory and prepaid expenses of \$1.2 million, \$0.2 million and \$0.2 million, respectively, as we increased our revenue, partially offset by adjustments for depreciation of \$0.5 million, preferred stock interest of \$3.9 million and a net increase in payables and accrued liabilities of \$0.3 million due to our increase in operating expenses.

**Cash flows used in investing activities.** Net cash used in investing activities was approximately \$14.8 million in 2005, \$1.5 million in 2004 and \$1.3 million in 2003. For each of these periods, cash used in investing activities reflected purchases of property and equipment and, in 2005, the purchase of approximately \$6.4 million of short-term investments, and the acquisition of Enable for a net purchase price of approximately \$6.4 million.

**Cash flows provided by financing activities.** Cash flows provided by financing activities were approximately \$44.6 million in 2005, \$89,000 in 2004 and \$18,000 in 2003. Cash flows provided by financing activities during 2005 were attributable to the proceeds from the issuance of common stock related to our initial public offering and borrowings under our Lighthouse credit facility discussed below, which were partially offset by payments made on our debt and lease obligations. For each of these periods, cash flows provided by financing activities also reflected the issuance of common stock related to stock option exercises.

**Credit facility.** We entered into a \$5.0 million credit facility on March 8, 2005 with Lighthouse Capital Partners V, L.P. for working capital requirements. Outstanding borrowings under the facility bear interest at the prime rate plus 1.75% and our ability to draw down funds under this facility terminated upon our initial public offering. Under the terms of the facility, we are required to pay any monthly installments of interest only through August 2005 and monthly installments of principal and interest thereafter, in addition to a fee due at maturity on September 1, 2009 equal to 15% of the aggregate amount borrowed under the credit facility, with prepayment in whole allowed at any time without penalty. As of December 31, 2005, there was approximately \$1.4 million outstanding under this facility.

In connection with establishing this facility, we granted Lighthouse a warrant to purchase 55,208 shares of our common stock, or shares into which such series of stock is converted, at a price of \$11.29 per share. In valuing this warrant, we relied upon recognized option pricing models. The valuations used closed-form models, such as the Black-Scholes-Merton model and the Bjerk Sund and Stensland approximation model, as well as the lattice form binomial models. The time to expiration of the warrant ranges between 1.0 year and 7.0 years, and we assumed values for volatility and expected dividend yield equal to 35.0% and 0%, respectively. The risk-free discount rate used ranged between 3.23% and 4.22%. Utilizing these inputs in the option-pricing models for the warrant, a value for the warrant of approximately \$3.91 per underlying share was determined, which has been recorded as deferred financing costs and will be amortized over the term of the credit facility.

In addition, we granted Lighthouse a first perfected lien on all our tangible and intangible assets, including accounts receivable, inventory, equipment, furniture and fixtures, but excluding intellectual property.

**Uses of liquidity and capital resources.** Our future capital requirements depend on a number of factors, including possible acquisitions and joint ventures, the rate of market acceptance of our current and future products, the resources we devote to developing and supporting our products, future expenses to expand and support our sales and marketing efforts, costs relating to changes in regulatory policies or laws that affect our operations and costs of filing, prosecuting, defending and enforcing our intellectual property rights. We expect to increase capital expenditures consistent with our anticipated growth in research and development, manufacturing, infrastructure and personnel. In addition, we acquired Enable contemporaneously with the closing of our initial public offering for a net purchase price of \$6.4 million.

We believe that our current cash and cash equivalents, along with the cash we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. If these sources of cash are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Additional financing may not be available at all, or in amounts or terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned research and development and selling and marketing efforts.

## Contractual Obligations and Commitments

The following sets forth our approximate aggregate obligations at December 31, 2005 for future payments under contracts and other contingent commitments:

Contractual Obligations	Total	Payments Due by December 31,				
		2006	2007	2008	2009	2010*
Long-term debt <sup>(1)</sup>	\$1,608,231	\$ 366,207	\$366,142	\$396,532	\$479,350	\$ —
Capital leases <sup>(2)</sup>	78,380	36,698	27,788	13,894	—	—
Operating lease <sup>(3)</sup>	1,422,319	400,742	394,984	331,646	253,250	41,697
Employment agreements <sup>(4)</sup>	750,000	750,000	—	—	—	—
Purchase obligation <sup>(5)</sup>	726,857	726,857	—	—	—	—
Royalty obligation <sup>(6)</sup>	800,000	200,000	200,000	200,000	200,000	—
Total contractual obligations	<u>\$5,385,787</u>	<u>\$2,480,504</u>	<u>\$988,914</u>	<u>\$942,072</u>	<u>\$932,600</u>	<u>\$41,697</u>

\* There are no contractual obligations after year 2010.

- (1) Represents principal repayment and a 15% fee due at maturity, which are required under the terms of our credit facility with Lighthouse Capital Partners V, L.P. In addition to principal and fees, we pay interest at the prime rate plus 1.75%. See Note 8 to the financial statements included herein.
- (2) Represents principal and interest payments required for our leases of manufacturing machinery and equipment. See Note 9 to the financial statements included herein.
- (3) Represents rent payments required for our office, manufacturing and storage facilities under the terms of our operating leases. See Note 9 to the financial statements included herein.
- (4) Represents salary and retention bonus payments payable under the terms of employment agreements executed by us as part of our acquisition of Enable Medical Corporation.
- (5) Represents payments required under the terms of a development and license agreement with UST Inc. See Note 9 to the financial statements included herein.
- (6) Represents payments required under the terms of a royalty agreement between us and Randall K. Wolf, M.D. for our use of the Wolf dissector. See Note 9 to the financial statements included herein.

## Off-Balance-Sheet Arrangements

As of December 31, 2005, we did not have any off-balance-sheet arrangements.

## Inflation

Inflation has not had a significant impact on our operations over the past three years and we do not expect it to have a significant impact on our results of operations or financial condition in the foreseeable future.

## Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On a periodic basis, we evaluate our estimates, including those related to accounts receivable, inventories and stock based compensation. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

**Stock-Based Compensation.** We account for employee stock options using the intrinsic value method in accordance with Accounting Principles Board ("APB") No. 25, Accounting for Stock Issued to Employees, Financial Accounting Standards ("FASB") Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, and related interpretations. Prior to January 1, 2006, we followed the disclosure-only provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock Based Compensation, as amended.

The information regarding net loss as required by SFAS No. 123, presented in Note 1 to our financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123(R), Share Based Payment (revised 2004), in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

**Revenue Recognition.** Revenue is generated primarily from the sale of our disposable Isolator ablation clamps, the Isolator bipolar pen and the Wolf dissector. Pursuant to our standard sales terms, revenue is recognized when title to the goods and risk of loss transfer to customers and there are no remaining obligations that will affect the customer's final acceptance of the sale. Our standard sales terms define the transfer of title and risk of loss to occur upon shipment to the respective customer. We maintain no post-shipping obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by us subsequent to shipment to the customer in order to render it operational. Product revenue includes shipping revenue of approximately \$141,000 in 2005, \$87,000 in 2004 and \$43,000 in 2003. Cost of freight is included in cost of goods sold. We sell our products through a direct and indirect sales force. Sales terms are consistent for both end-users and distributors, with terms generally not exceeding 120 days. Customers and distributors generally have no right of return.

We comply with SEC Staff Accounting Bulletin No. 101, Recognition in Financial Statements, or SAB 101, as amended by SAB 104. SAB 101 sets forth guidelines on the timing of revenue recognition based upon factors such as passage of title, installation, payment terms and ability to return products. We recognize revenue when all of the following criteria are met: persuasive evidence that an arrangement exists; delivery of the products or services has occurred; the selling price is fixed or determinable; and collectibility is reasonable assured.

**Allowance for Uncollectible Accounts Receivable.** We periodically and systematically evaluate the collectibility of accounts receivable and determine the appropriate reserve for doubtful accounts. In determining the amount of the reserve, we consider historical credit losses, the past due status of the receivables, and other customer-specific information, and any other relevant factors or considerations.

**Inventory Valuation.** Inventories are stated at the lower of cost or market using the first-in, first-out, or FIFO, cost method and consist of raw materials, work in process and finished goods. Reserves are estimated for excess, slow-moving and obsolete inventory, as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when the product is destroyed. We review inventory on hand at least quarterly and record provisions for excess and obsolete inventory based on several factors including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration. Our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of product approvals, variability in product launch strategies, product recalls and variation in product utilization all impact the estimates related to excess and obsolete inventory.

**Deferred Tax Asset Valuation Allowance.** Our estimate for the valuation allowance for deferred tax assets requires us to make significant estimates and judgments about our future operating results. Our ability to realize the deferred tax assets depends on our future taxable income as well as limitations on their utilization. A deferred tax asset is reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of our operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for our

products, competitive conditions, product development efforts, approvals of regulatory agencies, and product cost. If actual results differ from these projections, or if our expectations of future results change, it may be necessary to adjust the valuation allowance.

### **Recent Accounting Pronouncements**

In November 2004, the FASB issued SFAS No. 151 entitled "Inventory Costs." This Statement amends the guidance in ARB No. 43, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs and wasted material (spoilage). The provisions of this Statement will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We have not yet determined the impact that adopting SFAS No. 151 will have on our financial position and results of operations.

In December 2004, the FASB issued a revision to SFAS 123, "Share-Based Payment" ("SFAS 123(R)"). The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. SFAS 123(R) eliminates the alternative method of accounting for employee share-based payments previously available under APB No. 25 ("APB 25"). In April 2005, the SEC delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. As a result, SFAS 123(R) will be effective for us beginning in the first quarter of fiscal 2006. We expect this standard to have a significant impact on the statements of operations and statements of cash flows.

In March 2005, the FASB issued FASB Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations" ("FIN 47"). This Interpretation clarifies that an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability's fair value can be reasonably estimated. The provisions of this Interpretation were effective for calendar-year companies no later than the end of fiscal years ending after December 31, 2005. The adoption of FIN 47 did not have a material impact on our financial statements.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections—A Replacement of Accounting Principles Board (APB) Opinion No. 20 and SFAS 3." SFAS 154 requires retrospective application to prior periods' financial statements for a change in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. Additionally, retrospective application is not required when explicit transition requirements specific to newly adopted accounting principles exist. Retrospective application requires the cumulative effect of the change on periods prior to those presented to be reflected in the carrying amounts of assets and liabilities as of the beginning of the first period presented and the offsetting adjustments to be recorded to opening retained earnings. SFAS 154 retains the guidance contained in APB No. 20 for reporting both the correction of an error in previously issued financial statements and a change in accounting estimate. SFAS 154 will become effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We are required to adopt the provisions of SFAS 154, as applicable, beginning in the first quarter of fiscal 2006. The adoption of SFAS No. 154 is not expected to have a material impact on our financial statements.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions.

For the year ended December 31, 2005, none of our sales were denominated in currencies other than U.S. dollars. Although all of our sales and purchases are currently denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States. We invest our excess cash primarily in U.S. government securities, corporate bonds and commercial paper. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**ATRICURE, INC.**

**INDEX TO FINANCIAL STATEMENTS**

	<u>Page</u>
<b><i>Financial Statements:</i></b>	
Report of Independent Registered Public Accounting Firm .....	64
Consolidated Balance Sheets .....	65
Consolidated Statements of Operations .....	66
Consolidated Statements of Shareholders' Equity (Deficit) .....	67
Consolidated Statements of Cash Flows .....	68
Notes to Consolidated Financial Statements .....	69
<b><i>Financial Statement Schedule:</i></b>	
Schedule II Valuation and Qualifying Accounts .....	85

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of  
AtriCure, Inc.:

We have audited the accompanying consolidated balance sheets of AtriCure, Inc. and subsidiary (the "Company") as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Deloitte & Touche LLP  
Cincinnati, Ohio  
March 30, 2006

**ATRICURE, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2005 and 2004**

	<u>2005</u>	<u>2004</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 27,432,948	\$ 5,175,177
Short-term investments .....	6,369,234	—
Accounts receivable, less allowance for doubtful accounts of \$261,707 and \$56,779 as of December 31, 2005 and 2004, respectively .....	4,865,065	3,520,621
Inventories, net .....	2,135,143	1,087,408
Other current assets .....	845,330	112,740
Total current assets .....	<u>41,647,720</u>	<u>9,895,946</u>
Property and equipment, net .....	3,359,549	2,410,051
Deferred offering costs .....	—	412,005
Intangible assets .....	986,778	—
Goodwill .....	3,840,837	—
Other assets .....	205,531	12,618
Total assets .....	<u>\$ 50,040,415</u>	<u>\$ 12,730,620</u>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable (a) .....	\$ 1,243,365	\$ 733,444
Accrued liabilities .....	4,131,633	2,572,329
Current maturities of capital lease obligation .....	31,753	—
Current maturities of long-term debt .....	366,207	—
Total current liabilities .....	<u>5,772,958</u>	<u>3,305,773</u>
Capital lease obligation .....	38,855	—
Long-term debt .....	1,045,150	—
Redeemable preferred stock:		
Preferred stock, \$0.001 par value; designated Series A, 2,182,521 shares authorized, issued and outstanding as of December 31, 2004 .....	—	7,979,396
Preferred stock, \$0.001 par value; designated Series B, 4,059,720 shares authorized; 3,829,499 issued and outstanding as of December 31, 2004 .....	—	28,776,745
Total redeemable preferred stock .....	<u>—</u>	<u>36,756,141</u>
Shareholders' equity (deficit):		
Common stock, \$0.001 par value, 90,000,000 and 10,526,315 shares authorized as of December 31, 2005 and 2004, respectively; 12,086,482 and 1,880,169 issued and outstanding as of December 31, 2005 and 2004, respectively .....	12,086	1,880
Additional paid-in capital .....	86,107,520	3,281,447
Unearned compensation .....	(599,591)	(981,612)
Other comprehensive income .....	826	—
Accumulated deficit .....	<u>(42,337,389)</u>	<u>(29,633,009)</u>
Total shareholders' equity (deficit) .....	<u>43,183,452</u>	<u>(27,331,294)</u>
Total liabilities and shareholders' equity (deficit) .....	<u>\$ 50,040,415</u>	<u>\$ 12,730,620</u>

(a) Includes the following liabilities resulting from transactions with Enable Medical Corporation prior to the acquisition as of August 10, 2005:

Accounts payable .....	\$ —	\$ 434,869
------------------------	------	------------

See notes to financial statements.



**ATRICURE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2005, 2004, and 2003**

	2005	2004	2003
Revenues .....	\$ 30,956,987	\$19,157,032	\$ 9,792,350
Cost of revenues (a) .....	8,056,680	5,201,562	2,612,303
Gross profit .....	<u>22,900,307</u>	<u>13,955,470</u>	<u>7,180,047</u>
Operating expenses:			
Research and development expenses (a) .....	9,108,600	4,422,014	2,500,969
Selling, general and administrative expenses .....	<u>24,594,489</u>	<u>15,169,157</u>	<u>8,036,358</u>
Total operating expenses .....	<u>33,703,089</u>	<u>19,591,171</u>	<u>10,537,327</u>
Loss from operations .....	(10,802,782)	(5,635,701)	(3,357,280)
Preferred stock interest expense .....	(2,332,254)	(3,905,169)	(3,905,169)
Interest expense .....	(110,335)	—	—
Interest income .....	524,471	105,926	154,377
Other income .....	<u>84,868</u>	<u>—</u>	<u>—</u>
Loss before income taxes .....	(12,636,032)	(9,434,944)	(7,108,072)
Income tax expense .....	<u>(46,932)</u>	<u>(16,924)</u>	<u>—</u>
Net loss available to common shareholders .....	<u>\$(12,682,964)</u>	<u>\$(9,451,868)</u>	<u>\$(7,108,072)</u>
Basic and diluted loss per share .....	<u>\$ (2.10)</u>	<u>\$ (5.17)</u>	<u>\$ (3.97)</u>
Weighted average shares outstanding:			
Basic and diluted .....	<u>6,025,300</u>	<u>1,828,452</u>	<u>1,791,577</u>

(a) Includes the following expenses resulting from transactions with Enable Medical Corporation prior to the acquisition as of August 10, 2005:

Cost of revenues .....	\$4,259,269	\$4,941,341	\$2,568,407
Research and development expenses .....	\$1,201,583	\$1,228,659	\$ 981,593

See notes to financial statements.

**ATRICURE, INC.**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)  
YEARS ENDED DECEMBER 31, 2005, 2004, and 2003**

	<u>Common Stock</u>		<u>Additional</u>	<u>Unearned</u>	<u>Accumulated</u>	<u>Other</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in Capital</u>	<u>Compensation</u>	<u>Deficit</u>	<u>Comprehensive</u>	<u>Equity</u>
						<u>Income</u>	<u>(Deficit)</u>
Balance—December 31, 2002 . . . .	1,785,066	\$ 1,785	\$ 1,145,950		\$(12,997,806)		\$(11,850,071)
Proceeds from exercise of stock options to purchase common stock . . . . .	20,776	21	17,572				17,593
Accretion of issuance costs— preferred stock . . . . .					(29,292)		(29,292)
Issuance of stock options for services provided . . . . .			33,000				33,000
Net loss available to common shareholders . . . . .					(7,108,072)		(7,108,072)
Balance—December 31, 2003 . . . .	1,805,842	1,806	1,196,522		(20,135,170)		(18,936,842)
Proceeds from exercise of stock options to purchase common stock . . . . .	74,327	74	89,109				89,183
Intrinsic value of stock options granted . . . . .			1,308,816	\$(1,308,816)			—
Issuance of stock options for services provided . . . . .			687,000				687,000
Amortization of intrinsic value of stock options granted . . . . .				327,204			327,204
Accretion of issuance costs— preferred stock . . . . .					(45,971)		(45,971)
Net loss available to common shareholders . . . . .					(9,451,868)		(9,451,868)
Balance—December 31, 2004 . . . .	1,880,169	1,880	3,281,447	(981,612)	(29,633,009)		(27,331,294)
Proceeds from exercise of stock options to purchase common stock and warrants . . . . .	44,293	44	42,170				42,214
Intrinsic value of stock options granted . . . . .			216,211	(216,211)			—
Adjustment to intrinsic value of stock options granted due to cancellations . . . . .			(338,992)	338,992			—
Issuance of stock options for services provided . . . . .			413,962				413,962
Amortization of intrinsic value of stock options granted . . . . .				259,240			259,240
Accretion of issuance costs— preferred stock . . . . .					(21,416)		(21,416)
Warrants . . . . .			216,083				216,083
Initial public offering of common stock . . . . .	4,150,000	4,150	43,172,844				43,176,994
Conversion of preferred stock to common stock . . . . .	6,012,020	6,012	39,103,795				39,109,807
Unrealized gains on available-for-sale investments . . . . .						\$826	826
Net loss available to common shareholders . . . . .					(12,682,964)		(12,682,964)
Balance—December 31, 2005 . . . .	<u>12,086,482</u>	<u>\$12,086</u>	<u>\$86,107,520</u>	<u>\$ (599,591)</u>	<u>\$(42,337,389)</u>	<u>\$826</u>	<u>\$ 43,183,452</u>

See notes to financial statements.

**ATRICURE, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2005, 2004, and 2003**

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Cash flows from operating activities:			
Net loss .....	\$(12,682,964)	\$(9,451,868)	\$(7,108,072)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation .....	1,434,323	962,355	538,048
Amortization of intangible assets .....	83,222	—	—
Amortization of warrants .....	36,693	—	—
Loss on disposal of equipment .....	303,008	16,561	15,203
Stock compensation .....	673,199	1,014,204	33,000
Preferred stock interest .....	2,332,254	3,905,169	3,905,169
Changes in assets and liabilities, excluding the effects of acquisition:			
Accounts receivable .....	92,432	(1,892,795)	(1,150,845)
Inventory .....	(193,559)	(448,413)	(183,955)
Prepaid expenses .....	(666,679)	97,482	(164,496)
Other current assets .....	(43,201)	—	—
Other assets .....	409,985	(417,453)	1,929
Accounts payable .....	27,911	454,730	(110,660)
Commissions payable .....	575,658	565,044	155,384
Accrued liabilities .....	1,809	1,394,913	270,684
Net cash used in operating activities .....	<u>(7,615,909)</u>	<u>(3,800,071)</u>	<u>(3,798,611)</u>
Cash flows from investing activities:			
Purchases of property & equipment .....	(1,951,733)	(1,513,273)	(1,253,634)
Purchases of available-for-sale securities .....	(6,368,408)	—	—
Cash paid for acquisition, net of cash acquired .....	(6,420,681)	—	—
Net cash used in investing activities .....	<u>(14,740,822)</u>	<u>(1,513,273)</u>	<u>(1,253,634)</u>
Cash flows from financing activities:			
Proceeds from long-term debt borrowings .....	1,500,000	—	—
Payments on long-term debt .....	(88,643)	—	—
Payments on capital lease obligations .....	(16,063)	—	—
Proceeds from stock offering .....	43,176,994	—	—
Proceeds from stock option exercises and warrants .....	42,214	89,183	17,593
Net cash provided by financing activities .....	<u>44,614,502</u>	<u>89,183</u>	<u>17,593</u>
Net increase (decrease) in cash and cash equivalents .....	22,257,771	(5,224,161)	(5,034,652)
Cash and cash equivalents—beginning of period .....	5,175,177	10,399,338	15,433,990
Cash and cash equivalents—end of period .....	<u>\$ 27,432,948</u>	<u>\$ 5,175,177</u>	<u>\$10,399,338</u>
Supplemental cash flow information:			
Cash paid for income taxes .....	\$ 311,000	\$ —	\$ —
Cash paid for interest .....	\$ 47,949	\$ —	\$ —
Warrants issued in connection with line of credit .....	\$ 216,083	\$ —	\$ —
Preferred stock conversion .....	\$ 39,109,808	\$ —	\$ —

See notes to financial statements.

## ATRICURE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Nature of the Business**—AtriCure, Inc. (the “Company”) was incorporated in the State of Delaware on October 31, 2000, as a spin-off of Enable Medical Corporation, to focus on the surgical treatment of atrial fibrillation. Atrial fibrillation (“AF”) is a rapid, irregular quivering of the upper chambers of the heart. The Company sells its medical devices to hospitals and medical clinics both in the United States of America and internationally. International sales were approximately \$2.7 million, \$1.4 million, and \$0.3 million in 2005, 2004, and 2003, respectively.

**Principles of Consolidation**—The consolidated financial statements include the accounts of the Company and its subsidiary. Intercompany accounts and transactions are eliminated.

**Cash and Cash Equivalents**—The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents in the accompanying financial statements.

**Short-Term Investments**—The Company places its investments primarily in U.S. Government securities, corporate notes and commercial paper. The Company classifies all investments as available-for-sale. Such investments are recorded at fair value, with unrealized gains and losses recorded as a separate component of stockholders’ equity (deficit). The Company recognizes gains and losses when these securities are sold using the specific identification method.

**Revenue Recognition**—Revenues are generated primarily from the sale of the Company’s disposable Isolator ablation clamps, the Isolator bipolar pen and the Wolf dissector. Pursuant to the Company’s standard sales terms, revenue is recognized when title to the goods and risk of loss transfer to customers and there are no remaining obligations that will affect the customer’s final acceptance of the sale. The Company’s standard sales terms define the transfer of title and risk of loss to occur upon shipment to the respective customer. The Company maintains no post-shipping obligations to the recipients of the products. No installation, calibration or testing of this equipment is performed by the Company subsequent to shipment to the customer in order to render it operational. Product revenue includes shipping revenue of approximately \$141,000, \$87,000 and \$43,000 in 2005, 2004, and 2003, respectively. Cost of freight is included in cost of goods sold. The Company sells its products through a direct and indirect sales force. Sales terms are consistent for both end-users and distributors, with terms generally not exceeding 120 days. Customers and distributors generally have no right of return.

The Company complies with the Securities and Exchange Commission (“SEC”) Staff Accounting Bulletin No. 101, “Recognition in Financial Statements” (“SAB 101”), as amended by SAB 104. SAB 101 sets forth guidelines on the timing of revenue recognition based upon factors such as passage of title, installation, payment terms and ability to return products. The Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectibility is reasonably assured.

**Allowance for Uncollectible Accounts Receivable**—The Company periodically and systematically evaluates the collectibility of accounts receivable and determines the appropriate reserve for doubtful accounts. In determining the amount of the reserve, the Company considers historical credit losses, the past due status of the receivables, other customer-specific information, and any other relevant factors or considerations.

**Inventory**—Inventories are stated at the lower of cost or market using the first-in, first-out (“FIFO”) cost method. Reserves are estimated for excess, slow moving and obsolete inventory as well as inventory with a carrying value in excess of its net realizable value. Write-offs are recorded when a product is destroyed. The Company reviews inventory on hand at least quarterly and records provisions for excess and obsolete inventory

## ATRICURE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

based on several factors including current assessment of future product demand, anticipated release of new products into the market, historical experience and product expiration.

**Property and Equipment**—Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed on the straight-line method for financial reporting purposes over the estimated useful lives of the assets, which range from three to seven years. Maintenance and repair costs are expensed as incurred.

Included in Property and Equipment are generators and cryo-units that are loaned at no cost to medical providers who use the Company's product. These generators and cryo-units are depreciated over three years. The three year life reflects the fact that the generators and cryo-units are run by internal computers and are programmed with software to regulate the power to the ablation clamps. As they are most similar to a computer, and the tolerance for imprecision is extremely low due to the nature of the work they perform, the Company anticipates that the estimated useful life cycle of these units will be approximately three years. Such depreciation is included in cost of sales. The total of such depreciation was approximately \$777,000, \$543,000, and \$225,000 in 2005, 2004 and 2003, respectively.

**Impairment of Long-Lived Assets (Other than Goodwill)**—The Company, using its best estimates based on reasonable and supportable assumptions and projections, reviews for impairment of property and equipment in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." In 2005, the Company recorded a charge of approximately \$266,000 for the impairment of certain obsolete tooling equipment. The Company did not recognize any impairment of property and equipment in 2004 and 2003.

**Goodwill and Intangible Assets**—Goodwill and indefinite lived intangible assets are not amortized, but are evaluated at least annually for impairment. Intangible assets with determinable useful lives are amortized on a straight line basis over the estimated periods benefited.

**Other Income**—The Company receives research grants, which are recognized as funds are expended and not as awarded by awarding agencies.

**Income Taxes**—Income taxes have been computed using the asset and liability method, under which deferred income taxes are provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. Deferred taxes are measured using provisions of currently enacted tax laws. A valuation allowance against deferred tax assets is recorded when it is more likely than not that such assets will not be fully realized. Tax credits are accounted for as a reduction of income taxes in the year in which the credit originates.

The Company's estimate for the valuation allowance for deferred tax assets requires it to make significant estimates and judgments about its future operating results. The Company's ability to realize the deferred tax assets depends on its future taxable income as well as limitations on their utilization. A deferred tax asset is reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. The projections of the Company's operating results on which the establishment of a valuation allowance is based involve significant estimates regarding future demand for the Company's products, competitive conditions, product development efforts, approvals of regulatory agencies, and product cost. If actual results differ from these projections, or if the Company's expectations of future results change, it may be necessary to adjust the valuation allowance.

**Earnings (Loss) Per Share**—Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Since the

# **ATRICURE, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Company has experienced losses for all periods presented, net loss per share excludes the effect of 1,610,895, 1,064,294, and 923,359 options in 2005, 2004 and 2003, respectively, because such options are anti-dilutive. Therefore the number of shares calculated for basic net loss per share is also used for the diluted net loss per share calculation. All share and per share amounts reflect the 1-for-3.8 reverse stock split that was effected on July 27, 2005.

**Comprehensive Loss**—Comprehensive loss for the year ended December 31, 2005 was as follows:

Net loss available to common shareholders .....	\$(12,682,964)
Unrealized gains on available-for-sale investments .....	826
Comprehensive loss .....	<u><u>\$(12,682,138)</u></u>

There were no components of other comprehensive loss for the years ended December 31, 2004 and 2003.

**Research and Development**—Research and development costs are expensed as incurred.

**Stock-Based Employee Compensation**—The Company accounts for its stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board (“APB”) No. 25, “Accounting for Stock Issued to Employees,” and its related interpretations. The Company has adopted the pro forma disclosure requirements of SFAS No. 123, “Accounting for Stock-Based Compensation.” Accordingly, compensation expense has been recognized in the financial statements for stock-based awards to employees based on the intrinsic value, if any, of the options issued. In December 2004, the Financial Accounting Standards Board (“FASB”) issued a revision to SFAS No. 123, “Share-Based Payment,” which is effective for the first quarter of fiscal 2006. The Company expects this standard to have a significant impact on the statements of operations and statements of cash flows.

SFAS No. 123 requires the disclosure of pro forma net income or loss as if the Company had adopted the fair value method. Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of the option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company’s stock option awards. These models also require subjective assumptions, including expected time to exercise, which greatly affect the calculated values. If the computed fair values of the stock-based awards had been amortized to expense over the vesting period of the awards, the effect would have been as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss available to common shareholders .....	\$(12,682,964)	\$(9,451,868)	\$(7,108,072)
Add: Stock-based employee compensation expense included in net loss available to common shareholders, net of related tax effect ..	259,240	327,204	—
Deduct: Stock-based employee compensation expense if the fair market method had been applied, net of related tax effects .....	<u>(452,616)</u>	<u>(357,000)</u>	<u>(18,000)</u>
Pro forma net loss available to common shareholders if the fair market method had been applied .....	<u><u>\$(12,876,340)</u></u>	<u><u>\$(9,481,664)</u></u>	<u><u>\$(7,126,072)</u></u>
Net loss per common share:			
Basic and diluted-as reported .....	\$ (2.10)	\$ (5.17)	\$ (3.97)
Basic and diluted-pro forma .....	\$ (2.14)	\$ (5.19)	\$ (3.98)

# **ATRICURE, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

In calculating the compensation costs under SFAS No. 123, the fair value of the options is estimated on the grant date using the Black-Scholes option pricing model considering the following weighted average assumptions:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Risk free interest rates .....	1.98-3.99%	1.00 to 3.25%	0.59 to 1.98%
Expected lives (years) .....	4-6	1-4	1-4
Volatility .....	0%-57%	0.00%	0.00%
Dividend yield .....	0.00%	0.00%	0.00%

Based on the assumptions noted above, the weighted average fair value of the options granted during the year was as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Weighted average fair value of options granted .....	\$6.34	\$9.14	\$0.11

**Use of Estimates**—The preparation of the financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Reclassification**—Certain amounts in the accompanying financial statements and notes thereto have been reclassified to conform to the current year presentation.

**Fair Value Disclosures**—The fair value of the Company's assets and liabilities approximates the carrying values.

**Deferred Offering Costs**—The Company had deferred expenses, primarily legal fees, incurred in connection with its filing of a registration statement to sell common shares. These costs reduced the proceeds of the common stock offering (see Note 3).

## **2. ACQUISITION OF ENABLE MEDICAL CORPORATION**

On August 10, 2005, the Company acquired all of the outstanding shares of Enable Medical Corporation ("Enable"). The results of operations for Enable have been included in the Company's Statements of Operations since that date. Enable was a related party and is the manufacturer of the Company's single-use disposable ablation clamps (refer to Note 12). As a result of the acquisition, the Company expects to gain better control over manufacturing and supply chain activities, as well as enhance its engineering capabilities.

The Company paid approximately \$6.4 million to acquire Enable, net of \$0.8 million cash acquired. The aggregate purchase price was \$7.0 million, of which \$0.5 million was paid in February 2005 and the remaining \$6.5 million was paid in August 2005. The Company also incurred legal and professional expenses associated with the acquisition of approximately \$0.2 million. The purchase price reflects the expected growth potential of Enable and its profitability. As a result of this, the purchase price was in excess of the fair market value of the assets acquired, and the Company recorded goodwill of approximately \$3.8 million.

# **ATRICURE, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed on August 10, 2005.

Current assets .....	\$2,361,762
Property and equipment .....	660,612
Goodwill .....	3,840,837
Intangible assets .....	1,070,000
Other assets .....	11,502
Assets acquired .....	<u>7,944,713</u>
Current liabilities .....	1,437,361
Capital lease obligation .....	86,671
Liabilities assumed .....	<u>1,524,032</u>
Cash paid, less cash acquired .....	<u>\$6,420,681</u>

Intangible assets are currently estimated to be approximately \$1.1 million and consist of proprietary manufacturing technology, which is being amortized on a straight-line basis over 5 years. Amortization expense was approximately \$83,000 in 2005. The proprietary manufacturing technology was valued based on Enable's unique ability to manufacture the products to meet the Company's close tolerance specifications for surgical products. Enable developed an expertise in plating, mold, adhesive, and assembly technology that permitted it to be the sole supplier to the Company. The Company has utilized the income approach in conjunction with the excess earnings approach to value the cash flow attributable to the proprietary manufacturing technology. The Company has identified the product line revenues and the relevant costs and expenses and deducted the required returns on other contributing assets from the free cash flows, deriving the residual cash flows generated from the proprietary manufacturing technology assets, to which a discount rate was applied to determine a present value. Future amortization expense related to these intangible assets will be approximately \$214,000 in 2006-2009, and \$131,000 in 2010.

The following table summarizes unaudited pro forma financial information assuming the Enable acquisition had occurred on January 1, 2004. The unaudited pro forma information is based on information currently available and assumptions that the Company believes are reasonable. This unaudited pro forma information does not necessarily represent what would have occurred if the transaction had taken place on the dates presented and should not be taken as representative of future combined results of operations.

	<u>2005</u>	<u>2004</u>
Revenues .....	\$ 31,163,628	\$19,611,285
Net loss available to common shareholders .....	\$(11,996,151)	\$(8,508,737)
Basic and diluted loss per share .....	\$ (1.99)	\$ (4.65)

### **3. INITIAL PUBLIC OFFERING**

On August 10, 2005, the Company consummated an initial public offering of 4.6 million shares of its common stock at \$12.00 per share, which included the underwriters' exercise of their over-allotment option on August 9, 2005 to purchase 600,000 shares of the Company's common stock, of which 450,000 shares were sold by selling shareholders and 150,000 shares were sold by the Company. The Company did not receive any proceeds from the sale of the 450,000 shares of common stock that were sold by selling shareholders. These share amounts reflect a 1-for-3.8 reverse split of the capital stock that was affected on July 27, 2005. In connection with the offering, all of the 6,012,020 outstanding shares of preferred stock were converted into



# **ATRICURE, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

6,012,020 shares of common stock. Proceeds to the Company from the offering, after deducting underwriting discounts, commissions and offering expenses, were approximately \$43.2 million. Offering expenses were approximately \$3.1 million.

### **4. INVESTMENTS**

Investments consisted of the following at December 31, 2005:

	<u>Cost Basis</u>	<u>Unrealized Gains</u>	<u>Unrealized Losses</u>	<u>Fair Value</u>
Commercial paper (maturities between 90 days and one year) .....	\$2,428,992	\$6,119	\$ —	\$2,435,111
US Government securities (maturities between 90 days and one year) .....	1,998,467	—	(2,217)	1,996,250
Corporate notes (maturities between 90 days and one year) ...	1,940,949	—	(3,076)	1,937,873
Total .....	<u>\$6,368,408</u>	<u>\$6,119</u>	<u>\$(5,293)</u>	<u>\$6,369,234</u>

The Company had no short-term investments in 2004, and the Company has not experienced any significant realized gains or losses on its investments in the periods presented in the statements of operations.

### **5. INVENTORIES**

Inventories consisted of the following at December 31:

	<u>2005</u>	<u>2004</u>
Raw material .....	\$ 363,270	\$ —
Work in process .....	663,109	—
Finished goods .....	1,108,764	1,087,408
Total inventory .....	<u>\$2,135,143</u>	<u>\$1,087,408</u>

### **6. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following at December 31:

	<u>2005</u>	<u>2004</u>
Machinery and equipment .....	\$ 4,984,633	\$ 3,463,964
Computers and other office equipment .....	652,227	400,517
Furniture and fixtures .....	262,013	153,471
Leasehold improvements .....	142,190	39,353
Equipment under capital lease .....	102,429	—
Construction in progress .....	153,083	—
Total .....	6,296,575	4,057,305
Less accumulated depreciation .....	(2,937,026)	(1,647,254)
Property and equipment, net .....	<u>\$ 3,359,549</u>	<u>\$ 2,410,051</u>

# **ATRICURE, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

### **7. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following at December 31:

	<u>2005</u>	<u>2004</u>
Accrued commissions .....	\$ 987,599	\$ 791,639
Accrued bonus .....	600,813	236,268
Accrued vacation .....	469,049	175,698
Other accrued liabilities .....	<u>2,074,172</u>	<u>1,368,724</u>
Total accrued liabilities .....	<u>\$4,131,633</u>	<u>\$2,572,329</u>

### **8. FINANCING ARRANGEMENTS**

In March 2005, the Company entered into a credit facility with Lighthouse Capital Partners V, L.P. of up to \$5,000,000, to be drawn down by the earlier of an initial public offering of common stock and September 1, 2005. This credit facility is secured by substantially all of the Company's assets, excluding intellectual property. The interest rate for any amounts drawn down is the prime rate plus 1.75% fixed and determined on the date of the draw down. For all amounts drawn down, the interest rate is 8.0%. Under the credit facility, the Company was required to pay monthly installments of interest only through August 2005 and monthly installments of principal and interest thereafter, in addition to a fee due at maturity on September 1, 2009 equal to 15% of the aggregate amount borrowed under the credit facility, with prepayment in whole allowed at any time without penalty. As of December 31, 2005, there was approximately \$1.4 million outstanding under this facility.

In addition, the facility required the Company to issue to Lighthouse a warrant to purchase 55,208 shares of common stock at an exercise price of \$11.29 per share. The warrant is exercisable at any time until August 10, 2006.

In connection with establishing this facility, the Company granted Lighthouse a warrant to purchase 55,208 shares of its common stock, or shares into which such series of stock is converted, at a price of \$11.29 per share. In valuing this warrant, the Company relied upon recognized option pricing models. The valuations used closed-form models, such as the Black-Scholes-Merton model and the Bjerk Sund and Stensland approximation model, as well as the lattice form binomial models. The time to expiration of the warrant ranges between 1.0 year and 7.0 years, and the Company assumed values for volatility and expected dividend yield equal to 35.0% and 0%, respectively. The risk-free discount rate used ranged between 3.23% and 4.22%. Utilizing these inputs in the option-pricing models for the warrant, a value for the warrant of approximately \$3.91 per underlying share was determined, which has been recorded as deferred financing costs and will be amortized over the term of the credit facility.

Maturities under this facility for the next five fiscal years are as follows:

2006 .....	\$ 366,207
2007 .....	366,142
2008 .....	396,532
2009 .....	<u>282,476</u>
Total long-term debt .....	1,411,357
Less: Current portion of debt .....	<u>366,207</u>
Long-term portion of debt .....	<u>\$1,045,150</u>

**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**9. COMMITMENTS AND CONTINGENCIES**

***Leases***

As a result of the Enable acquisition, the Company assumed Enable's capital leases for manufacturing machinery and equipment. As of December 31, 2005, the cost of the assets under lease was \$102,429. These assets are amortized over the estimated useful life of the asset, and such amortization is included in depreciation expense. Depreciation and accumulated depreciation on the capital leases were \$8,495 at December 31, 2005. The future minimum annual rentals under capital lease obligations for leases in place as of December 31, 2005 are as follows:

2006 .....	\$36,698
2007 .....	27,788
2008 .....	13,894
	<u>78,380</u>
Less portion of payments representing interest .....	<u>7,772</u>
Present value of lease payments .....	70,608
Less current portion .....	<u>31,753</u>
Long-term lease obligations .....	<u>\$38,855</u>

The Company entered into a noncancelable operating lease for its corporate headquarters facility that expires in 2009. As a result of the Enable acquisition, the Company acquired additional fabrication and office facilities with noncancelable operating leases expiring in 2010. In addition to the Company's facilities, the Company leases office equipment and has a 24-month lease for an off-site data storage space that expires at the end of 2007. Future minimum lease payments on operating leases are approximately \$400,700 in 2006, \$395,000 in 2007, \$331,600 in 2008, \$253,300 in 2009, and \$41,700 in 2010. There are no payments scheduled after 2010.

Rent expense was approximately \$205,500, \$98,600, and \$75,300 in 2005, 2004, and 2003, respectively.

***Purchase Obligations***

In June 2005, the Company entered into a 19-month development agreement with Stellartech Research Corporation whereby Stellartech agreed to develop enhancements to the current ASU technology and granted the Company a license to use Stellartech's technology in the field of cardiac arrhythmia treatment. The Company agreed to pay Stellartech on an hourly basis, based on the types of services being performed. In addition, materials and components, out-of-pocket expenses and outside services will be billed to the Company at cost plus a specified percentage. The Company may terminate this agreement upon 30 days' notice and have no minimum purchase obligations. Under the terms of this agreement, the Company has certain indemnification obligations to Stellartech for its performance of services under the agreement, except for Stellartech's breach, fraud, negligence or misconduct and infringement relating to intellectual property owned by Stellartech, for each of which it indemnifies the Company.

In June 2005, the Company also entered into a manufacturing agreement with Stellartech whereby the Company agreed, among other things, to purchase, and Stellartech agreed to supply, the first 400 Ablation Sensing Units, or ASUs, that the Company requires. As of December 31, 2005, the Company had fulfilled its obligation to purchase the first 400 ASUs from Stellartech and was required to purchase at least 75% of its ASU requirements from Stellartech until November 2007. The Company may, however, extinguish its obligation to purchase 75% of its ASU requirements from Stellartech by paying to Stellartech either a certain percentage of the gross margin Stellartech would have received if it had manufactured the ASUs or a specified dollar amount. This

## ATRICURE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

agreement has an initial three-year term and renews for successive one-year periods, unless terminated. This agreement may be terminated by Stellartech for any reason upon six months' notice to the Company. The Company may terminate the agreement in the event the development agreement is terminated prior to expiration or after the Company has fulfilled the purchase requirements under the agreement. Under the terms of this agreement, the Company has certain indemnification obligations, including with respect to claims relating to intellectual property infringement, design defects and manufacturing defects. Any supply interruption or failure to obtain the Company's ASU would limit the Company's ability to sell its system and could have a material adverse effect on its business, financial condition and results of operations.

In July 2005, the Company entered into a development and license agreement with UST Inc., whereby UST agreed to design and develop a high intensity focused ultrasound, or HIFU, system to create certain types of lesions and granted the Company an exclusive, worldwide license to related technology. The Company agreed to pay UST an initial development fee of \$375,000 and an additional development fee of \$966,000, payable in fourteen monthly installments. If UST has not completed its development services within fourteen months, the Company will be required to pay UST the direct costs incurred by it for the following six months in connection with continuing to render development services. The Company is also required to pay UST royalties of 4% of the net sales of the HIFU system, up to a maximum amount of \$15 million in royalties during the royalty term. In addition, the Company is required to make certain license and maintenance payments to UST for the sublicenses granted to it under the terms of this agreement. The Company may terminate this agreement at any time by giving notice to UST. UST may terminate this agreement if the Company fails to timely commercialize the HIFU system or if the Company fails to timely pursue FDA approval or clearance of the HIFU system. Under the terms of this agreement, the Company has certain indemnification obligations to UST for its breach of this agreement. In order to commercialize this HIFU system, the Company may be required to license additional intellectual property from third parties. The Company cannot assure you that it will be able to license this technology on commercially reasonable terms, if it all.

#### ***Royalty Obligation***

In October 2005, the Company entered into a royalty agreement with Randall K. Wolf, M.D., who is the co-inventor of the Company's Wolf dissector. Under the terms of the agreement, the Company is required to make minimum quarterly payments of \$50,000 for the use of the Wolf dissector as well as for those inventions, improvements or ideas made or conceived by Dr. Wolf within the field of atrial fibrillation treatment. Royalty payments may exceed the \$50,000 minimum and are based on a percentage of the Company's net sales of the Wolf dissector. The royalty rate declines over the life of the agreement and was 15.0% in the fourth quarter of 2005, and will be 10.5% in 2006, 4.0% in 2007, 2.5% in 2008 and 1.5% in 2009. The royalty agreement terminates on December 31, 2009, and total payments under the agreement shall not exceed \$2,000,000. The Company expensed \$85,000 under this agreement in 2005.

#### ***Legal***

##### ***Settlement with a Competitor***

A competitor filed a suit against the Company in August 2005 that sought an injunction to prevent the Company from continuing to employ its former employee as a sales representative and made related claims against the employee and the Company, including requests for damages in an unspecified amount. The Company and the other parties involved in this suit entered into a settlement agreement and mutual release effective November 18, 2005, which did not have a material adverse effect upon the Company.

##### ***Life Support Technology LST B.V.***

In January 2006 Life Support Technology LST B.V. ("LST"), a former distributor of the Company's products in Europe, filed an action against the Company in Den Bosch, Netherlands and in February, 2006 LST

## **ATRICURE, INC.**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

also filed an action against the Company's subsidiary, AtriCure Europe, B.V. ("AtriCure Europe") in The Hague, Netherlands in the Kort Geding. On March 28, 2006, the case against AtriCure Europe was summarily dismissed. LST has until April 25, 2006 to file for an appeal of this decision.

The Company and LST were party to a distribution agreement, dated January 1, 2004. Each of LST's summonses allege that the Company, on behalf of AtriCure Europe, and LST reached an agreement, which would succeed a January 1, 2004 agreement, pursuant to which LST agreed to continue distributing the Company's in certain European countries. The summonses allege that, in addition to the value for LST of a continued distributorship, such agreement would have provided an additional \$330,000 to LST and its principal, J.L.M. Marinus. The Company believes that neither the Company nor the Company's subsidiary reached such an agreement with LST and that the original distribution agreement with LST was terminated as of December 31, 2005. The Company intends to defend these lawsuits vigorously.

Pursuant to the Company's January 1, 2004 distribution agreement with LST, certain of LST's obligations survive termination of that agreement. Such obligations include, among other things, the timely payment for equipment purchased and the return of all materials (such as marketing literature and sales and promotional materials) supplied by the Company to LST. In March 2006 the Company filed a complaint in Ohio State Court (Butler County, Ohio Court of Common Pleas) against LST claiming that LST has not complied with these obligations and the Company is seeking monetary damages from LST.

#### **10. REDEEMABLE PREFERRED STOCK**

In 2001, the Company issued 2,182,521 shares of Series A Preferred Stock at \$2.39 per share. In exchange for the Series A Preferred Stock, the Company received \$4,025,000 in cash and converted a \$1,150,000 promissory note that was issued in January 2001 and the related accrued interest of \$49,958. The proceeds were reduced by \$131,426 in direct expenses associated with the offering. Amortization of the direct issuance expenses was \$12,058, \$23,572, and \$16,428 in 2005, 2004, and 2003, respectively.

In 2002, the Company issued 3,829,499 shares of Series B Preferred Stock at \$5.43 per share. In exchange for the Series B Preferred Stock, the Company received \$17,274,500 in cash and converted a \$3,500,000 note and the related accrued interest of \$35,000. The proceeds were reduced by \$96,704 in direct expenses associated with the initial public offering. Amortization of the direct issuance expenses was \$9,358, \$22,399, and \$12,864 in 2005, 2004, and 2003, respectively.

Each share of Series A and B Preferred Stock was convertible by the holders into common stock of the Company at any time after the date of issuance. The number of shares of common stock that would be received upon conversion would have been determined by dividing \$2.39 by the Series A conversion price and \$5.43 by the Series B conversion price (original issue price subject to adjustments as specified in the Company's Certificate of Incorporation) in effect at the time of conversion. In addition, upon conversion, the holder of each share of Series A or B Preferred Stock would have received cash in an amount equal to all dividends declared but unpaid and any and all other amounts owing with respect to the Series A or B Preferred Stock. Upon the closing of the Company's initial public offering, all of the 6,012,020 outstanding shares of preferred stock were converted into 6,012,020 shares of common stock, as discussed above in Note 3.

The holders of at least two-thirds of the then issued and outstanding shares of Series A or a majority of the then issued and outstanding shares of Series B Preferred Stock may have caused the Company, beginning on June 6, 2007, and on each of the first and second anniversaries thereof, to redeem from the holders of the Series A or B Preferred Stock at a price equal to the original Series A or B Preferred Stock purchase price plus all declared or accrued but unpaid dividends and an amount equal to 15% per annum (by simple interest calculation) of the original Series A or B per share purchase price from the date of May 25, 2001 (Series A) and June 6, 2002

# **ATRICURE, INC.**

## **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

(Series B), through and until the redemption date. The 15% rate was payable only if the Series A or B Preferred Stock was redeemed. Since the Series A and B Preferred Stock were converted prior to redemption, no amount was due for the 15% rate. Pursuant to their terms, the Series A and B Preferred Stock converted into shares of common stock on a one-for-one basis upon completion of the initial public offering since the Company received gross proceeds of at least \$35,000,000. The preferred stock was converted to common stock on the initial public offering date and the carrying amount of the preferred stock was reclassified to common stock. There was no gain or loss recognized, and the amounts accrued in prior periods for the 15% return were not reversed.

Increases in the cumulative Series A preferred stock, included in the accompanying financial statements, for the 15% rate were \$468,069 in 2005 and \$783,744 in both 2004 and 2003. Increases in the Series B preferred stock, included in the accompanying financial statements, for the 15% rate were \$1,864,185 in 2005 and \$3,121,425 in both 2004 and 2003.

## **11. INCOME TAXES**

Deferred income tax assets and liabilities are computed annually for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

Deferred tax assets result from an operating loss carryforward and research and development credits. The detail of deferred tax assets and liabilities at December 31, 2005 and 2004 is as follows:

	<u>2005</u>	<u>2004</u>
Net operating loss carryforward . . . . .	\$ 8,323,000	\$ 5,544,000
Research and development credit carryforward . . . . .	1,095,000	585,000
Stock compensation . . . . .	444,000	111,000
Accruals and reserves . . . . .	342,000	76,000
Intangible assets . . . . .	(355,000)	—
Other-net . . . . .	32,000	(48,000)
Subtotal . . . . .	9,881,000	6,268,000
Less valuation allowance . . . . .	(9,881,000)	(6,268,000)
Total . . . . .	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2005, 2004, and 2003, the Company recorded a valuation allowance of approximately \$9,881,000, \$6,268,000, and \$4,313,000, respectively, due to the uncertainty of when these assets may be realized.

The expense for income taxes is as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Current state tax expense . . . . .	\$ 46,932	\$ 16,924	\$ —
Deferred tax benefit . . . . .	(3,613,000)	(1,956,000)	(832,000)
Increase in valuation allowance . . . . .	3,613,000	1,956,000	832,000
Total . . . . .	<u>\$ 46,932</u>	<u>\$ 16,924</u>	<u>\$ —</u>

## **ATRICURE, INC.**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The Company has a Federal net operating loss carryforward of approximately \$23,654,000 which will begin to expire in 2021. The Company also has State net operating losses of approximately \$14,760,000 which have varying expirations ranging from 5 years to 20 years. The Company also has a research and development credit carryforward of approximately \$1,095,000 which will begin to expire in 2021.

#### **12. RELATED PARTY**

Prior to the acquisition, Enable was a related party with whom the Company transacted business.

In November 2000, the Company entered into a rental and administrative services agreement with Enable, whereby the Company obtained access and use of facility, personnel, and systems from Enable. This agreement expired in January 2003. In January 2002 (amended in 2003), the Company entered into a master development, manufacturing, and supply agreement with Enable. Pursuant to the terms of the development, manufacturing, and supply agreement with Enable, the Company was required to pay Enable a monthly fee of at least \$96,000 for certain product development services during the period from February 1, 2003 to January 31, 2004. After January 31, 2004 there was no specified monthly fee requirement. The agreement expired in January 2005, but was extended to December 2005 in February 2005. The agreement was cancelled as of August 10, 2005 in connection with the acquisition.

#### **13. PROFIT SHARING PLAN**

The Company sponsors a defined contribution savings and profit sharing retirement plan. Eligible employees may contribute up to 15% of their eligible compensation. For every dollar contributed by a participant, the Company will match a fixed percentage set prior to the end of the fiscal year (50% of the first 6% for 2005, 2004, and 2003, respectively). The Company may also make discretionary contributions. Total Company matching and discretionary contributions charged to expense were approximately \$243,500, \$107,700, and \$75,000 in 2005, 2004, and 2003, respectively.

#### **14. EQUITY COMPENSATION PLANS**

As of December 31, 2005 the Company had two equity compensation plans; the 2001 Stock Option Plan (the "2001 Plan") and the 2005 Equity Incentive Plan (the "2005 Plan"). The 2001 plan has lapsed as to the granting of options.

Under the 2005 Plan, the Board of Directors may grant incentive stock options to employees and any parent or subsidiary's employees, and may grant nonstatutory stock options, stock purchase rights, restricted stock, stock appreciation rights, performance units or performance shares to employees, directors and consultants of the Company and any parent or subsidiary's employees, directors and consultants. The administrator (which is made up of the Company's board of directors or a committee of the board) has the power to determine the terms of any awards, including the exercise price of options, the number of shares subject to each award, the exercisability of the awards and the form of consideration.

Options granted under the 2001 and 2005 Plans generally expire 10 years from the date of grant (5 years for persons owning more than 10% of the voting power of all classes of stock) and generally vest at a rate of 25% on the first anniversary date and ratably each year or month thereafter. Certain options are exercisable upon grant and the underlying unvested shares are subject to the Company's repurchase right as stated in the applicable plan agreement.

Under the 2005 Plan, 1,750,000 shares of common stock have been reserved for issuance. In addition, the shares reserved for issuance under the 2005 plan include (a) shares reserved but unissued under the 2001 Plan as

**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

of August 10, 2005, (b) shares returned to the 2001 Plan as the result of termination of options or the repurchase of shares issued under such plan, and (c) annual increases in the number of shares available for issuance on the first day of each year equal to the lesser of:

- 3.25% of the outstanding shares of common stock on the first day of the fiscal year;
- 825,000 shares; or
- An amount the Company's board may determine.

As of December 31, 2005, 2004, and 2003, 3,092,105, 1,342,105 and 1,184,211 shares, respectively, of the Company's common stock have been reserved for issuance under the Company's equity compensation plans.

Activity under the Plans was as follows:

	2005 Stock Options Outstanding		2004 Stock Options Outstanding		2003 Stock Options Outstanding	
	Number of Shares Outstanding	Weighted Average Exercise Price	Number of Shares Outstanding	Weighted Average Exercise Price	Number of Shares Outstanding	Weighted Average Exercise Price
Outstanding—Beginning of the year . . . .	1,064,294	\$ 1.44	923,359	\$1.21	819,747	\$1.14
Granted . . . . .	688,082	12.67	253,474	2.38	217,500	1.52
Forfeited . . . . .	(97,188)	3.91	(38,211)	1.82	(93,112)	1.48
Exercised . . . . .	(44,293)	0.95	(74,328)	1.22	(20,776)	0.84
Outstanding—end of year . . . . .	<u>1,610,895</u>	<u>\$ 6.10</u>	<u>1,064,294</u>	<u>\$1.44</u>	<u>923,359</u>	<u>\$1.22</u>
Exercisable—end of year . . . . .	<u>662,998</u>		<u>444,827</u>		<u>304,234</u>	

At December 31, 2005, 2004, and 2003, there were 1,311,556, 150,503, and 207,872 shares, respectively, available for future grants under the Plans.

Additional information regarding stock options outstanding as of December 31, 2005 is as follows:

Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Exercisable at December 31, 2005
\$ 0.57	150,520	5.25	150,520
0.63	52,631	5.24	52,631
1.90	4,999	5.94	4,999
3.80	5,262	6.08	3,946
1.33	406,440	6.75	305,159
1.52	234,467	8.66	123,707
2.09	22,630	8.42	5,657
2.66	28,998	8.60	7,250
3.23	32,570	8.84	9,129
11.29	96,972	9.26	—
11.63	16,664	9.27	—
12.35	34,202	9.45	—
12.00	122,534	9.60	—
13.89	108,812	9.71	—
12.10	3,944	9.87	—
13.18	289,250	9.94	—
	<u>1,610,895</u>		<u>662,998</u>



## ATRICURE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The exercise price per share of each option is equal to the fair market value of the underlying share on the date of grant. For options granted prior to the Company's initial public offering, the board determined the fair market value based on a multiple of revenues reduced by a factor due to the illiquidity of the options in a private company with no assurances of public market.

For the years ended December 31, 2005 and 2004, the Company incurred a charge for stock compensation for employees for options issued with exercise prices below market value. The Company recorded a charge of approximately \$259,000 and \$327,000, which represents the portion pertaining to the years ended December 31, 2005 and 2004, respectively, based on the options' vesting requirements.

**Stock Compensation**—The Company has issued nonstatutory common stock options to consultants to purchase shares of common stock. Such options vest over a service period ranging from immediately to four years. The fair value, which is subject to adjustment at each vesting date based upon the fair value of the Company's common stock, was determined using the Black-Scholes valuation model with the following weighted average assumptions: contractual life of ten years; volatility ranging from 0% to 57%; risk-free interest rate ranging from 1% to 3.99% and no dividends during the expected term. The values attributable to these options have been amortized over the service period on a graded vesting method and the vested portion of these options was re-measured at each vesting date.

Stock compensation expense with respect to non-employee awards totaled approximately \$414,000, \$687,000 and \$33,000 in 2005, 2004, and 2003, respectively.

### 15. RECENT ACCOUNTING PRONOUNCEMENTS

In November 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, "Inventory Costs." This Statement amends the guidance in Accounting Research Bulletin No. 43, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight handling costs and wasted material (spoilage). The provisions of this Statement will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company has not yet determined the impact that adopting SFAS No. 151 will have on its financial position and results of operations.

In December 2004, the FASB issued a revision to SFAS 123, "Share-Based Payment" ("SFAS 123(R)"). The revision requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. SFAS 123(R) eliminates the alternative method of accounting for employee share-based payments previously available under APB No. 25 ("APB 25"). In April 2005, the SEC delayed the effective date of SFAS 123(R) to fiscal years beginning after June 15, 2005. As a result, SFAS 123(R) will be effective for the Company beginning in the first quarter of fiscal 2006. The Company expects this standard to have a significant impact on the statements of operations and statements of cash flows.

In March 2005, the FASB issued FASB Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations" ("FIN 47"). This Interpretation clarifies that an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability's fair value can be reasonably estimated. The provisions of this Interpretation were effective for calendar-year companies no later than the end of fiscal years ending after December 31, 2005. The adoption of FIN 47 did not have a material impact on the Company's financial statements.

In May 2005, the FASB issued SFAS 154, "Accounting Changes and Error Corrections—A Replacement of APB Opinion No. 20 and SFAS 3." SFAS 154 requires retrospective application to prior periods' financial statements for a change in accounting principle, unless it is impracticable to determine either the period-specific

**ATRICURE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

effects or the cumulative effect of the change. Additionally, retrospective application is not required when explicit transition requirements specific to newly adopted accounting principles exist. Retrospective application requires the cumulative effect of the change on periods prior to those presented to be reflected in the carrying amounts of assets and liabilities as of the beginning of the first period presented and the offsetting adjustments to be recorded to opening retained earnings. SFAS 154 retains the guidance contained in APB No. 20 for reporting both the correction of an error in previously issued financial statements and a change in accounting estimate. SFAS 154 will become effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's financial statements.

**16. SEGMENT AND GEOGRAPHIC INFORMATION**

The Company considers reporting segments in accordance with SFAS 131, "Disclosure about Segments of an Enterprise and Related Information." The Company's system and devices are developed and marketed to a broad base of hospitals in the United States and internationally. Management considers all such sales to be part of a single operating segment.

Geographic revenue is as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
United States .....	\$28,281,096	\$17,748,472	\$9,478,294
International .....	2,675,891	1,408,560	314,056
Total .....	<u>\$30,956,987</u>	<u>\$19,157,032</u>	<u>\$9,792,350</u>

Substantially all of the Company's long-lived assets are located in the United States.

**SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**  
(Dollars in thousands, except per share data)

	For the Three Months Ended							
	March 31,		June 30,		September 30,		December 31,	
	2005	2004	2005	2004	2005	2004	2005	2004
<b>Operating Results:</b>								
Revenue .....	\$ 7,498	\$ 3,802	\$ 7,730	\$ 5,125	\$ 7,170	\$ 4,500	\$ 8,559	\$ 5,730
Gross profit .....	5,578	2,712	5,752	3,739	5,154	3,338	6,416	4,166
Net loss available to common shareholders .....	(2,366)	(2,130)	(2,343)	(1,174)	(3,964)	(2,662)	(4,010)	(3,486)
<b>Loss per share (Basic and Diluted):</b>								
Basic and diluted loss per share .....	\$ (1.26)	\$ (1.18)	\$ (1.24)	\$ (0.65)	\$ (0.49)	\$ (1.46)	\$ (0.33)	\$ (1.86)

**SCHEDULE II**  
**VALUATION AND QUALIFYING ACCOUNTS**

	<u>Beginning Balance</u>	<u>Additions</u>	<u>Deductions</u>	<u>Ending Balance</u>
<b>Allowance for doubtful accounts receivable</b>				
Year ended December 31, 2005 .....	\$ 56,779	\$ 204,928	\$ —	\$ 261,707
Year ended December 31, 2004 .....	\$ 27,877	\$ 28,902	\$ —	\$ 56,779
Year ended December 31, 2003 .....	\$ —	\$ 27,877	\$ —	\$ 27,877
<b>Allowance for inventory valuation</b>				
Year ended December 31, 2005 .....	\$ —	\$ 287,052	\$ 28,494	\$ 258,558
Year ended December 31, 2004 .....	\$ —	\$ —	\$ —	\$ —
Year ended December 31, 2003 .....	\$ —	\$ —	\$ —	\$ —
<b>Valuation allowance for deferred tax assets</b>				
Year ended December 31, 2005 .....	\$6,268,000	\$3,661,000	\$ 48,000	\$9,881,000
Year ended December 31, 2004 .....	\$4,313,000	\$1,955,000	\$ —	\$6,268,000
Year ended December 31, 2003 .....	\$3,481,000	\$ 832,000	\$ —	\$4,313,000

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this Form 10-K was carried out under the supervision and with the participation of our management, including our chief executive officer and chief financial officer. Based on that evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level to ensure that material information relating to us, is made known to them, particularly during the period in which this Form 10-K was prepared, in order to allow timely decisions regarding required disclosure.

### **Changes in Internal Control Over Financial Reporting**

During our most recent fiscal quarter, there has not occurred any change in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) under the Securities Exchange Act of 1934) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 9B. OTHER INFORMATION**

None.

### **PART III**

#### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information required by this Item is incorporated by reference to the definitive proxy statement for our 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our 2005 fiscal year (the "2005 Proxy Statement").

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is incorporated by reference to the 2005 Proxy Statement.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item is incorporated by reference to the 2005 Proxy Statement.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information required by this Item is incorporated by reference to the 2005 Proxy Statement.

#### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item is incorporated by reference to the 2005 Proxy Statement.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (1) The financial statements required by Item 15(a) are filed in Item 8 of this Form 10-K.
- (2) The financial statement schedules required by Item 15(a) are filed in Item 8 of this Form 10-K.
- (3) The following exhibits are included herein or incorporated herein by reference:

<u>Exhibit No.</u>	<u>Description</u>
1.1	Underwriting Agreement, dated as of August 5, 2005, between AtriCure, Inc., the Selling Stockholders as named therein and the Underwriters as named therein.
2.1 <sup>(1)</sup>	Agreement and Plan of Merger, dated as of February 14, 2005, between AtriCure, Inc. and Enable Medical Corporation (exhibits and schedules have been omitted but will be furnished supplementally to the Securities and Exchange Commission upon request).
2.1.1 <sup>(2)</sup>	First Amendment to Agreement and Plan of Merger between AtriCure, Inc. and Enable Medical Corporation.
3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Second Amended and Restated Bylaws.
4.1 <sup>(1)</sup>	Amended and Restated Investors' Rights Agreement, dated June 6, 2002 between AtriCure, Inc. and each of the signatory Investors.
4.1.1 <sup>(1)</sup>	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated March 8, 2005 between AtriCure, Inc. and each of the signatory Investors.
4.4 <sup>(2)</sup>	Specimen common stock certificate.
4.5 <sup>(1)</sup>	Specimen of warrant certificate issued to former Series B preferred shareholders.
4.6 <sup>(1)</sup>	Specimen of warrant certificate issued to Lighthouse Capital Partners V, L.P.
10.1 <sup>(1)</sup> #	2001 Stock Option Plan.
10.2 <sup>(2)</sup> #	2005 Equity Incentive Plan.
10.3 <sup>(2)</sup> †	Development Agreement, dated as of June 1, 2005, between AtriCure, Inc. and Stellartech Research Corporation.
10.4 <sup>(2)</sup> †	Manufacturing Agreement, dated as of June 1, 2005, between AtriCure, Inc. and Stellartech Research Corporation.
10.6 <sup>(1)</sup>	Lease Agreement, dated as of December 18, 2000, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.6.1 <sup>(1)</sup>	Agreement to Improve Lease Premises, First Amendment to Lease Dated December 18, 2000, dated as of May 28, 2002, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.6.2 <sup>(1)</sup>	Agreement to Expand Leased Premises and Extend Lease, Second Amendment to Lease Dated December 18, 2000, dated as of April 8, 2004, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.7 <sup>(1)</sup>	Loan and Security Agreement No. 4631, dated as of March 8, 2005, by and between Lighthouse Capital Partners V, L.P. and AtriCure, Inc.

<u>Exhibit No.</u>	<u>Description</u>
10.8 <sup>(2)†</sup>	Master Development, Manufacturing and Supply Agreement, Second Amended and Restated, dated as of March 19, 2003 by and between Enable Medical Corporation and AtriCure, Inc.
10.9 <sup>(2)†</sup>	Technology Transfer Agreement, dated as of May 25, 2001, by and between AtriCure, Inc. and Enable Medical Corporation.
10.10 <sup>(3)</sup>	Development and License Agreement, dated as of July 15, 2005, by and between AtriCure, Inc. and UST Inc.
10.11†	Royalty Agreement, dated as of November 21, 2005, by and between AtriCure, Inc. and Randall K. Wolf, M.D.
21	Subsidiaries of the Registrant
23.1	Consent of Deloitte & Touche LLP
31.1	Rule 13a-14(a) Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Rule 13a-14(a) Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Executive Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Financial Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on April 20, 2005, which was declared effective on August 4, 2005.

(1) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on June 14, 2005, which was declared effective on August 4, 2005.

(2) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 7, 2005, which was declared effective on August 4, 2005.

(3) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 19, 2005, which was declared effective on August 4, 2005.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

# Compensatory plan or arrangement.



## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K to be signed on our behalf by the undersigned, thereunto duly authorized.

**AtriCure, Inc.**  
(REGISTRANT)

Date: March 31, 2006

/s/ David J. Drachman

**David J. Drachman**  
President and Chief Executive Officer

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David J. Drachman and Thomas J. Etergino, his attorneys-in-fact, with the power of substitution, for him in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, and any of them or his substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities indicated on March 31, 2006:

<u>Signature</u>	<u>Title(s)</u>
<u>/s/ Richard M. Johnston</u> Richard M. Johnston	<b>Richard M. Johnston</b> <i>Chairman of the Board</i>
<u>/s/ David J. Drachman</u> David J. Drachman	<b>David J. Drachman</b> <i>Chief Executive Officer (principal executive officer)</i>
<u>/s/ Thomas J. Etergino</u> Thomas J. Etergino	<b>Thomas J. Etergino</b> <i>Chief Financial Officer (principal financial and accounting officer)</i>
<u>/s/ Michael D. Hooven</u> Michael D. Hooven	<b>Michael D. Hooven</b> <i>Director</i>
<u>/s/ Donald C. Harrison</u> Donald C. Harrison	<b>Donald C. Harrison</b> <i>Director</i>
<u>/s/ Alan L. Kaganov</u> Alan L. Kaganov	<b>Alan L. Kaganov</b> <i>Director</i>
<u>/s/ Mark R. Lanning</u> Mark R. Lanning	<b>Mark R. Lanning</b> <i>Director</i>
<u>/s/ Karen P. Robards</u> Karen P. Robards	<b>Karen P. Robards</b> <i>Director</i>
<u>/s/ Norman R. Weldon</u> Norman R. Weldon	<b>Norman R. Weldon</b> <i>Director</i>
<u>/s/ Lee R. Wrubel</u> Lee R. Wrubel	<b>Lee R. Wrubel</b> <i>Director</i>

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
1.1	Underwriting Agreement, dated as of August 5, 2005, between AtriCure, Inc., the Selling Stockholders as named therein and the Underwriters as named therein.
2.1 <sup>(1)</sup>	Agreement and Plan of Merger, dated as of February 14, 2005, between AtriCure, Inc. and Enable Medical Corporation (exhibits and schedules have been omitted but will be furnished supplementally to the Securities and Exchange Commission upon request).
2.1.1 <sup>(2)</sup>	First Amendment to Agreement and Plan of Merger between AtriCure, Inc. and Enable Medical Corporation.
3.2*	Amended and Restated Certificate of Incorporation.
3.4*	Second Amended and Restated Bylaws.
4.1 <sup>(1)</sup>	Amended and Restated Investors' Rights Agreement, dated June 6, 2002 between AtriCure, Inc. and each of the signatory Investors.
4.1.1 <sup>(1)</sup>	Amendment No. 1 to Amended and Restated Investors' Rights Agreement, dated March 8, 2005 between AtriCure, Inc. and each of the signatory Investors.
4.4 <sup>(2)</sup>	Specimen common stock certificate.
4.5 <sup>(1)</sup>	Specimen of warrant certificate issued to former Series B preferred shareholders.
4.6 <sup>(1)</sup>	Specimen of warrant certificate issued to Lighthouse Capital Partners V, L.P.
10.1 <sup>(1)</sup> #	2001 Stock Option Plan.
10.2 <sup>(2)</sup> #	2005 Equity Incentive Plan.
10.3 <sup>(2)</sup> †	Development Agreement, dated as of June 1, 2005, between AtriCure, Inc. and Stellartech Research Corporation.
10.4 <sup>(2)</sup> †	Manufacturing Agreement, dated as of June 1, 2005, between AtriCure, Inc. and Stellartech Research Corporation.
10.6 <sup>(1)</sup>	Lease Agreement, dated as of December 18, 2000, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.6.1 <sup>(1)</sup>	Agreement to Improve Lease Premises, First Amendment to Lease Dated December 18, 2000, dated as of May 28, 2002, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.6.2 <sup>(1)</sup>	Agreement to Expand Leased Premises and Extend Lease, Second Amendment to Lease Dated December 18, 2000, dated as of April 8, 2004, between AtriCure, Inc. and Allen Road Properties Limited Liability Company.
10.7 <sup>(1)</sup>	Loan and Security Agreement No. 4631, dated as of March 8, 2005, by and between Lighthouse Capital Partners V, L.P. and AtriCure, Inc.
10.8 <sup>(2)</sup> †	Master Development, Manufacturing and Supply Agreement, Second Amended and Restated, dated as of March 19, 2003 by and between Enable Medical Corporation and AtriCure, Inc.
10.9 <sup>(2)</sup> †	Technology Transfer Agreement, dated as of May 25, 2001, by and between AtriCure, Inc. and Enable Medical Corporation.
10.10 <sup>(3)</sup>	Development and License Agreement, dated as of July 15, 2005, by and between AtriCure, Inc. and UST Inc.

<u>Exhibit No.</u>	<u>Description</u>
10.11†	Royalty Agreement, dated as of November 21, 2005, by and between AtriCure, Inc. and Randall K. Wolf, M.D.
21	Subsidiaries of the Registrant
23.1	Consent of Deloitte & Touche LLP
31.1	Rule 13a-14(a) Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Rule 13a-14(a) Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Executive Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification pursuant to 18 U.S.C. Section 1350 by the Chief Financial Officer, as adopted, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on April 20, 2005, which was declared effective on August 4, 2005.

(1) Incorporated by reference to Amendment No. 1 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on June 14, 2005, which was declared effective on August 4, 2005.

(2) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 7, 2005, which was declared effective on August 4, 2005.

(3) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form S-1 (Registration No. 333-124197), filed on July 19, 2005, which was declared effective on August 4, 2005.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

# Compensatory plan or arrangement.

INVESTOR RESOURCES

MANAGEMENT

INVESTOR RELATIONS CONTACT

ANNUAL MEETING

CORPORATE HEADQUARTERS

FORM 10-K

FINANCIAL STATEMENTS



AtriCure, Inc.  
6033 Schumacher Park Drive  
West Chester, OH 45069  
513.755.4100  
[www.atricure.com](http://www.atricure.com)